ELECTION 2020
What Pharmacy Needs From the Next Administration
THINK FIRST® BEFORE YOU COMPOUND

A comprehensive FAMILY of Single-Prescription Compounding Kits

Two additional family members:
FIRST® - Metronidazole  
FIRST® - Progesterone VGS

Compounding made quick & easy

✓ CONVENIENT
• Pre-weighed, pre-measured components
• One single product #/kit for easy prescription processing

✓ CONSISTENT
• Promotes accurate dosing each time
• Helps facilitate your obligations under 503A and USP <795>

Medicine that’s easy to give... AND TO TAKE

To learn more, visit FIRSTKITS.COM or call 1-800-461-7449

Azurity Pharmaceuticals®, Inc. was formerly known as CutsiPharma®, Inc. Product packaging may reflect either name.

© 2020 Azurity Pharmaceuticals®, Inc. All rights reserved.
CHAIRMAN’S LETTER

Celebrate and Advocate for the Pharmacy Profession

If anything has demonstrated the need and value of expanded access to community-based care, it’s been the coronavirus disease 2019 (COVID-19) pandemic.

Over the past several weeks, the passage of new legislation has highlighted pharmacists’ value to their communities. At the time of this publication, the US Department of Health & Human Services has authorized all state-licensed pharmacists the ability to administer pediatric immunizations, as well as COVID-19 vaccines once they are available. This is a significant step forward for the profession, as pharmacists will play a critical role in immunization efforts amid the COVID-19 response. However, for a long time, industry headwinds have impeded pharmacists’ ability to practice at the top of their licenses. As pharmacists begin to step into the role of clinicians, legislation should ensure that they are also compensated fairly for doing so.

In this issue, you’ll find coverage from ThoughtSpot Live 2020, AmerisourceBergen and Good Neighbor Pharmacy’s annual independent pharmacy conference and trade show, which includes an update on key areas of focus for independent pharmacies looking to thrive in today’s challenging environment. As pharmacies continue to pivot their services to adapt, supporting business expansion beyond the traditional dispensing will be crucial to success. Visit www.drugtopics.com/conference/thoughtspot for more insights, including interviews with leading experts.

Furthermore, on top of the ongoing public health crisis, the presidential election is looming. Our cover story on page 8 dives into how the outcome of this election might affect health care issues, especially for pharmacy. What happens next in health care depends largely on COVID-19, especially in light of breaking news at press time that the President has been diagnosed with COVID-19. No matter what, advocacy remains crucial to pharmacists overcoming current barriers, such as direct and indirect remuneration fees.

And finally, October is American Pharmacists Month—a dedicated time to recognize pharmacists’ contribution to health care. Take time to celebrate staff members going above and beyond. On page 28, Karen Berger, PharmD, writes more about how pharmacists can honor the profession throughout the month.

As always, visit drugtopics.com as we continue to keep you up-to-date with the latest pharmacy news.

Thank you for reading,

Mike Hennessy Sr
Chairman and Founder of MJH Life Sciences™
EDITORIAL MISSION: *Drug Topics®* is the top-ranked pharmacy resource for community and health-system professionals. Since 1857, readers have turned to *Drug Topics®* for coverage of issues and trends important to the practice of pharmacy, and for a forum in which they can share viewpoints and practical ideas for better pharmacy management and patient care.
CeraVe Celebrates You

Happy American Pharmacists Month and thank you for making us your #1 Pharmacist Recommended Brand.
Navigating diabetes management.
Trust the light.

The highly accurate\(^1\) and easy-to-use CONTOUR®NEXT ONE meter, with its unique smartLIGHT feature, instantly shows if blood glucose is in target range – which helps guide decision making.\(^2,3\)

Patients can get even more guidance with the CONTOUR®DIABETES app:
- **Improved** glucose control.\(^4\)
- **Increased engagement** with diabetes management.\(^4\)
- **Significant decrease** in likelihood of hypoglycemic events.\(^4\)

References:
2. Grady M et al. J Diabetes Sci Technol 2015;9:841-848 (Pg. 6, Table 2).
3. Ascensia Diabetes Care, Data on file, SMARTSON market research study of the CONTOUR®NEXT ONE meter and CONTOUR®DIABETES app, June 2017, Sweden. Participants received a free meter and test strips.

© 2020 Ascensia Diabetes Care. All rights reserved. Ascensia, the Ascensia Diabetes Care logo, and Contour are trademarks and/or registered trademarks of Ascensia Diabetes Care. Patients should consult with their health care provider prior to making changes to diet, exercise or treatment regimen.

* In a data analysis of people in North America using the CONTOUR®DIABETES app (N=5,970 people with diabetes), real world evidence demonstrated that use of the app for more than 180 days resulted in a statistically significant decrease in the estimated risk of experiencing >1 hypoglycemic or hyperglycemic event at using both the less (<70mg/dL and >180 mg/dL; n=1,253) and more stringent (<50mg/dL and >250 mg/dL; n=654) definitions of hypoglycemia and hyperglycemia, indicating improved blood glucose control.

Compatible with Apple Health™
Available With a Unique J-Code

EFFECTIVE JULY 1, 2020

PRODUCT-SPECIFIC BILLING CODE:
HCPCS code J9198 – Injection, gemcitabine hydrochloride (INFUGEM™), 100 mg

READY TO LEARN MORE?
GO TO WWW.INFUGEM.COM
HHS Permits Pharmacists to Order, Administer COVID-19 Vaccines

On September 9, the Department of Health and Human Services (HHS) authorized state-licensed pharmacists to order and administer, and state-licensed or registered pharmacy interns under the supervision of the pharmacist to administer, coronavirus disease 2019 (COVID-19) vaccines to individuals ages 3 or older.

The guidance was issued under the Public Readiness and Emergency Preparedness (PREP) Act and comes after HHS recently authorized all state-licensed pharmacists and pharmacy interns to order and administer childhood vaccinations amid the pandemic.

“This is tremendous news,” Scott J Knoer, MS, PharmD, FASHP, executive vice president and CEO of the American Pharmacists Association said in a statement. “It properly recognizes that pharmacists serve a vital role in the nation’s response to this pandemic. It increases patients’ access to care during this emergency with providers whom they trust, at a time and place that is convenient for them.”

Study Evaluates Americans’ Willingness to Receive COVID-19 Vaccine

Results of a recent study showed that approximately 7 in 10 Americans are willing to get a coronavirus disease 2019 (COVID-19) vaccine once available.

The study, which was published in Vaccine, included an online survey of more than 2000 adults ages 18 and older in the United States in May 2020. The survey asked participants about their willingness to be vaccinated and 11 factors that could influence that decision. Out of 2006 respondents, 1374 (69%) said they would “definitely” or “probably” get vaccinated. The survey results also showed that 17% were “not sure” and 14% were “probably” or “definitely” not willing.

Participants indicated they were more willing to get vaccinated if they thought their health care provider would recommend the vaccine or if they reported higher levels of perceived likelihood of becoming infected with COVID-19 in the future. Participants who identified as moderate or liberal in their political beliefs were also more willing to receive the vaccine. Those who reported a higher level of perceived potential vaccine harms were less likely to indicate willingness, according to the study.

Additionally, non-Latinx Black Americans were less likely to report willingness to receive the vaccine, with only 55% expressing willingness to get vaccinated. However, the investigators noted that vaccine acceptability was high among the Latinx population.
We represent independent pharmacies, leveraging our buying power to help them access pharmaceuticals at the best prices.

To evaluate and compare your current price file for free, please write to us at info@OmegaRxGroup.com

Omega Pharmacy Group

www.OmegaRxGroup.com

Contract negotiations and vendor relationship management

Analytical Reporting
What Pharmacy Needs From the Next Administration

By Fred Gebhart
cope of practice and vaccination authority don’t usually grab much public attention. But when the US Department of Health & Human Services (HHS) preempted state practice acts to allow all pharmacists to order and provide coronavirus disease 2019 (COVID-19) tests and provide routine pediatric immunizations, the profession hit the headlines. What happens next in health care depends largely on COVID-19, especially in light of the breaking news at press time that the President has been diagnosed with COVID-19. And then, of course, on the 2020 presidential election itself.

Presidential candidates regularly trade barbs on access to care, drug pricing, health insurance, and similar issues. But exactly how the 2 candidates, President Donald Trump and Joe Biden, might address health care issues is murky.

As vice president during the Obama administration, Biden was a strong supporter of the Affordable Care Act (ACA). As a candidate in 2020, he has called for broader access to health care and a national, science-based approach to the COVID-19 pandemic. Biden routinely wears a face mask in public and has called for a national policy favoring masks to reduce COVID-19 transmission.

As president, Trump has repeatedly criticized the ACA. When legislative attempts to derail ACA failed, the administration tried legal challenges. The Supreme Court will hear arguments to block the ACA in November.

On the COVID-19 front, the administration has taken contradictory positions. Trump has largely left pandemic response up to the states and said at the debate between he and Biden at the end of September, held days before his positive COVID-19 diagnosis, that he thinks masks are “ok,” and that he wore them when he thought they were needed. However, he has

“There have been a lot of flexibilities and gains that have been achieved for pharmacists and for patients during [COVID-19]. In the next administration, whether it’s the same party or a different party, we’re going to watch and push for those flexibilities and gains to be maintained [and] move to further gains that can continue to make a difference in patient care.”

ILISA BERNSTEIN, PHARM.D., JD, FAPHA, SENIOR VICE PRESIDENT OF PHARMACY PRACTICE AND GOVERNMENT AFFAIRS FOR THE AMERICAN PHARMACISTS ASSOCIATION
“The next administration needs to get rid of the barriers, the handcuffs, to allow everyone to pitch in as part of the provider team—nurses, doctors, pharmacists—to give patients the best possible care and the best possible outcomes.”

Ken Thai, PharmD, President of the California Pharmacists Association and Chief Executive Officer of 986 Pharmacy Corporation

administration responses to COVID-19 leave pharmacists, and everyone else, with more questions on health care policy in 2021 than answers.

“We are asking all the candidates about their positions on pharmacy issues, and we don’t have clear answers yet,” said Michael Jackson, RPh, executive vice president and chief executive officer of the Florida Pharmacists Association. “We do know that the status quo can’t remain. We have got to change dramatically.”

Change should start in the pharmacy supply chain and payment models, Jackson continued. Both presidential candidates, as well as other candidates up and down the ballot, have to recognize that pharmacy is not a cost center, but a cost container. Current payment models are driving pharmacies out of business.

Independent pharmacists have been complaining about direct and indirect remuneration (DIR) fees for years. More recently, chains and hospitals have added their objections. “It’s pretty dire when you get the entire pharmacy industry to stand behind one issue,” said Brian Caswell, RPh, president of the National Community Pharmacists Association (NCPA) and owner of 4 pharmacies in Kansas and Missouri.

“DIR fees mean that on a quarterly basis, you have somebody reach into your bank account and pull a big chunk of money out, which totally disrupts your budget [and your] plans to improve your business [and] make capital investments so you can step up and do a better job of taking care of your patients. Everyone is being hurt by DIR fees, including patients.”

Caswell noted that one of his stores lost $100,000 to DIR fees in 2019. That kind of unpredictable loss made him reconsider a $200,000 automated multidose strip-and-pouch packaging unit that could help ease adherence. No one knows how the next president might approach DIR fees.

“We have a president [whom] we know a little bit about related to pharmacy issues, and we have a candidate who wasn’t big in the pharmacy space in his previous elected positions,” said Karry La Violette, advocacy center director and senior vice president of Government Affairs for NCPA. “We have a lot of unknowns with Biden, but he wouldn’t be a hard sell. We know what we are getting with the Trump administration, sometimes unpredictable, but we know where they’re coming from.”

By the end of both parties’ conventions, neither candidate had staked out positions on DIR fees, pharmacy benefit manager (PBM) regulation, drug pricing, scope of practice, the 340B drug pricing program, or other key pharmacy issues. Neither the Trump nor Biden campaigns responded to repeated information requests for this article. But the two have very different perspectives on how health care should be delivered.

“You could have a President Biden focused on public options,” explained Tom Krause, JD, MHS, vice president of Government Relations for the American Society of Health-System Pharmacists (ASHP). “You could have a President Trump preserving some selected aspects of the ACA but overall opposing it. Trump has a preference for a very state-based approach to managing response to the COVID-19 pandemic. Signals we’re seeing from Biden would be a more nationally focused response. Those are fundamental contrasting visions of health care.”

Learning From COVID-19

If current trends continue, more than 200,000 Americans will have died from COVID-19 by election day on November 3. There are endless, unsolvable arguments over how many deaths might have been avoided had the federal government taken a different approach to the pandemic. But from the health care perspective, the pandemic has brought a few positives changes.
“Pharmacists have to speak their mind, talk to every one of their candidates at the local, state, and federal levels, [and] utilize their contacts to get our message out there. If we can move our solutions, our personal relationships with patients, to be unencumbered by the payment system, we’re going to see better outcomes, happier patients, and happier pharmacists.”

BRIAN CASWELL, RPH, PRESIDENT OF THE NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

When the federal government declared a public health emergency on January 31, HHS was able to make sweeping changes to the provision of and payment for health care services under the PREP Act.

HHS authorized physicians and other clinicians to practice in states in which they were not licensed under some circumstances and allowed pharmacists to order and administer COVID-19 tests. HHS later authorized pharmacists to provide point-of-care testing for influenza and COVID-19, expanded pharmacists’ authority to provide pediatric immunizations, and adapted reimbursement mechanisms to pay pharmacists directly for some COVID-19–related services.

“With the pandemic, pharmacists and pharmacies have been able to work as providers,” said Ilisa Bernstein, PharmD, JD, FAPhA, senior vice president of Pharmacy Practice and Government Affairs for the American Pharmacists Association (APhA). “There have been a lot of flexibilities and gains that have been achieved for pharmacists and for patients during COVID-19. In the next administration, whether it’s the same party or a different party, we’re going to watch and push for those flexibilities and gains to be maintained [and] move to further gains that can continue to make a difference in patient care.”

The problem is that COVID-19–related improvements in patient care all depend on the public health emergency. Once the emergency expires, state regulations take over. And not all states changed their regulatory approaches.

“There have been national mandates, but the actual changes to practice acts have not been uniform,” said Ken Thai, PharmD, president of the California Pharmacists Association and chief executive officer of 986 Pharmacy Corporation. “The next administration needs to get rid of the barriers, the handcuffs, to allow everyone to pitch in as part of the provider team—nurses, doctors, pharmacists—to give patients the best possible care and the best possible outcomes.”

Provider status has been on the pharmacy wish list for years. Bipartisan provider status legislation has been introduced in Washington but has never moved out of committee. California pharmacists gained provider status in 2014.

“Even 6 years later, recognizing that if we perform a service, we need to get paid for it, hasn’t happened to the extent that we have been able to unleash pharmacists’ true powers to help their patients,” Thai said. “With DIR fees, pharmacists are paying to provide services because there is negative reimbursement because of actions taken by the PBMs. I’m hoping this election highlights what we have been doing and the outcomes we have provided. For too many people, we haven’t just been the most available health care provider, we have been the only provider because so many physician practices were closed or limiting visits.”

Take Action

None of these changes will happen on their own. Political candidates don’t respond to stakeholders they don’t hear from. Pharmacists have to make their own case, time and again, until change happens.

APhA, ASHP, NCPA, and other pharmacy groups are lobbying both candidates, Krause said. ASHP has pointed out that a public option for health coverage has the potential to increase covered populations. That could expand government negotiating power when it comes to issues such as patient access and drug pricing.

AFA is emphasizing the improved patient outcomes that pharmacists and pharmacy have produced from the expanded flexibility and practice that authorities put into place during the pandemic.

Caswell at NCPA is pushing the need for pharmacists to speak individually as well as through their organizations.

“We have a pandemic that has become political, and pharmacists have to get involved,” Caswell said. “A Republican mantra for a long time has been local control. And a Democratic mantra has always been patient choice. That’s a perfect combination of working with the patient-provider decision-making process and we pharmacists have to be part of that discussion. Pharmacists have to speak their mind, talk to every one of their candidates at the local, state, and federal levels, and utilize their contacts to get our message out there. If we can move our solutions, our personal relationships with patients, to be unencumbered by the payment system, we’re going to see better outcomes, happier patients, and happier pharmacists.”
Independent pharmacists can now invest in technologies that result in more efficient practices, improved quality of care, and increased margins. In the last few years, competitors in e-commerce have entered the health care market by offering clinical and non-clinical products and services, including medication adherence packaging and free delivery.

Is adherence packaging technology a big investment for independent pharmacy? It depends. What follows are ways to manage and recover up-front costs.

**CHOOSE BUYING OR LEASING OPTIONS**

Reputable adherence packaging vendors such as RxSafe or Parata provide options to pharmacies for either a cash purchase or a capital lease to buy (use) the necessary equipment.

With a capital lease, the pharmacy maintains cash flow while building up a patient base to pay for the new service. A cash purchase and a capital lease option both provide the pharmacy 100% depreciation options in the tax year that the technology is placed in service.

**MAXIMIZE ADHERENCE PACKAGING SERVICES**

Community pharmacists can market adherence packaging services to a broad customer base such as senior living and nursing homes, group homes, mental health care facilities, and even correctional facilities in their market. These customers recognize the advantages of packaged meds with a time and date stamp specific to each patient. The style of packaging or dispensing can also be tailored to the patient’s needs, such as blister packs for patients with arthritis.

Such contracts, even when paired with free delivery services, can quickly cover up-front equipment costs while serving a broader community. The pharmacy can serve hundreds of patients in just one facility.

**Offer OTC or Supplement Options**

According to adherence packaging vendors, patients who take 7 or 8 regular prescriptions will provide a more immediate return on the investment than patients who only take 1 or 2 medications regularly.

Patients with fewer medications could choose from recommended nutritional supplements or OTC medications in their packaging. This approach helps pharmacies introduce patient preventative care and wellness as part of the service.

**Rightsize Your Staffing With Automation**

Automated, adherence packaging is also recommended for increasing efficiency. A robotic process can reduce staffing and related benefits expenses, or it can allow existing staff allocation to top-line cash clinical and nonclinical services.

When determining your pharmacy’s ability to invest in new technologies, take time to calculate the cost savings on staffing or the ability to launch new services with the same number of staff.

**Improve Star Ratings and Reduce DIR Fees**

By directly providing adherence packaging, the pharmacy maintains a vital direct link to patients for confidential and knowledgeable consultations.

On the business side, a pharmacy can also improve Star Ratings, reduce potential direct and indirect remuneration (DIR) fees, and, therefore, improve pharmacy bottom-line revenue. This is a long game, so it is important to seek guidance from your certified public accountant to determine when and how to bring an adherence packaging service in-house.

Adherence packaging is a clear technology disruptor, but consumer awareness is still fairly low. Consumers will be attracted to the convenience and ease, but pharmacies can help them realize the long-term health care benefits through local access and attention.
Remarkable accuracy.\textsuperscript{2,3} Always covered under Medicare Part B.*

Your patients with diabetes rely on you for blood glucose meter and test strip platform recommendations. When accuracy and ease of use are most important, prescribe CONTOUR\textsuperscript{®}NEXT test strips – always covered under Medicare Part B.

* Not a guarantee of coverage and payment. A doctor’s prescription is required for Medicare coverage and patients must meet Medicare eligibility coverage criteria. Coverage and payment may be subject to coinsurance, deductible and patient eligibility requirements. Visit http://www.medicare.gov to learn more about Medicare plans and coverage.

The correlation between obesity and various diseases (eg, cardiovascular disease, certain cancers, diabetes, etc) points to a growing public health crisis. Obesity is a leading risk factor for developing type 2 diabetes, thus offering tremendous opportunity for pharmacists to improve patient outcomes.

Patients now have a variety of options to help them lose weight. These include pharmaceuticals, invasive surgeries, minimally invasive implants and devices, and lifestyle modifications such as diet and exercise. Similarly, health and wellness services in pharmacy have surged in recent years, with pharmacists offering a variety of specialized services to support their patients’ needs.

**OFFER WEIGHT-FOCUSED WELLNESS COUNSELING**

Although counseling patients at the time of medication dispensing seems the most obvious time to educate on weight-focused wellness, it is frequently not practical. Some pharmacists carve out time slots dedicated to addressing individual patients’ needs by scheduling appointments. Planning is key, according to Christina Madison, PharmD, FCCP, AAHIVP, founder and CEO of The Public Health Pharmacist and associate professor of pharmacy practice at Roseman University of Health Sciences in Las Vegas, Nevada. Madison describes the ideal scenario as a private space where the pharmacist has allotted 15 to 20 minutes during an off-peak period. She encourages pharmacists to document the encounter and follow up with the patient, which includes recording the patient’s weight before the encounter and at follow-up.

Richard Harris, MD, PharmD, MBA, founder of Great Health and Wellness in Houston, Texas, noted that some pharmacists use these assigned times to conduct wellness checks, review medications, or discuss other issues the patient may be facing.

“There are some pharmacists and pharmacies that offer specific weight-loss programs,” Harris said. “They’ll do functional medicine, which is getting to the root cause of the issues, as well as holistic, lifestyle, or integrative medicine.”

Brian Bisher, PharmD, BCPS, a clinical pharmacist and an Institute for Integrative Nutrition–certified health coach in Cincinnati, Ohio, works at an area hospital that provides some of these services.

“I would label our clinic as a pharmacy-run service that offers weight-loss/nutrition services,” he said. “We set aside 30- to 60-minute appointments specifically for diabetes patient care management in our outpatient wellness clinic.”

Bisher’s clinic sometimes recruits a registered dietician as well. However, unlike some community practice settings, patients cannot receive such services without a referral from their physician.

**STOCK UP ON HIGH-QUALITY SUPPLEMENTS**

According to Harris, many pharmacies that offer these specialized services also carry high-quality, pharmaceutical-grade supplements—a feature he feels is critical, given the fact that OTC dietary health supplements are not regulated to the same degree of stringency as prescription pharmaceutical products.

“These are high-quality supplements you can trust,” Harris said of the supplements typically carried at pharmacy wellness centers. “There are plenty of these wellness centers out there, and the pharmacies that have these wellness centers are the ones I highly recommend people seek.”

Although they had different opinions about which supplements to stock in the pharmacy, Harris and Bisher did agree on a few products, namely, berberine. “Berberine is a supplement that can be used in place of metformin to start if a patient would prefer to use herbal therapy,” Bisher explained.

Results of a 2012 meta-analysis and systematic review concluded that berberine effectively treated hypoglycemia. However, more studies are needed to evaluate the safety of berberine in long-term use.
Berberine is an isoquinoline alkaloid compound isolated from rhizoma coptidis. Its hyperglycemia-mitigating effects were first documented in 1988 when it was used to treat diarrhea in patients with diabetes, and the extract’s antidiabetic potential has since been studied in a variety of clinical trials.\(^1\)

However, a search in ClinicalTrials.gov using the key words “berberine” and “diabetes mellitus type 2” only resulted in 5 studies on berberine. Two of those studies explored the compound’s effect on diabetes (NCT02084004 and NCT00425009). The first study was withdrawn, and the second study was completed in December 2004.\(^2,3\)

A different trial helped illustrate berberine’s clinical potential. The pilot study was divided into 2 studies with the goal of evaluating the safety and efficacy of berberine in patients with type 2 diabetes.\(^5\)

In study A, 36 adults who had received a recent diagnosis of type 2 diabetes were randomly assigned to receive either berberine or 0.5 g of metformin 3 times per day for 3 months. Berberine’s hypoglycemic activity mirrored that of metformin with statistically significant decreases in hemoglobin A1C (HbA\(_1c\); from 9.5% ± 0.5% to 7.5% ± 0.4%; \(P < .01\)). Patients in the berberine arm also experienced significant decreases in fasting blood glucose (FBG), postprandial blood glucose (PBG), and plasma triglycerides.

Forty-eight patients with poorly controlled type 2 diabetes were enrolled in the second study (study B) and received berberine supplements for 3 months. Similarly, biomarkers for blood sugar improved. FBG and PBG improved within 1 week and HbA\(_1c\) dropped (from 8.1% ± 0.2% to 7.3% ± 0.5%; \(P < .0001\)).\(^5\)

Consider These Counseling Tips

Educating patients during a consultation is the single most important service pharmacists can offer. What follows are several weight-management counseling points for patients with diabetes:

- Encourage patients to eat a whole foods diet. “If it doesn’t walk, swim, run, come from the ground, and it didn’t exist 100 years ago, don’t eat it,” said Harris. In other words, encourage patients to avoid processed foods and any foods that have chemical ingredients that “you would need a PhD to pronounce.”

- Educate patients on how to eat for weight loss. Madison recommended that pharmacists drive home the importance of limiting noncomplex carbohydrates and avoiding foods high in sugar. Proper fluid intake is also important.

- Groom the patient for success. “Making lifestyle changes is more easily said than done for people whose lifestyle is not currently aligned with these recommendations,” Bisher cautioned. “This is why I always recommend starting off with small changes, so the person can feel successful implementing them.” For example, focus on adding foods that are more ideal for their situation rather than suggesting the complete avoidance of certain foods.

- Consider the patient’s work schedule, home environment, sleep schedule, social interactions, and stress management. Discuss these factors with the patient and adjust their wellness plan accordingly.

- Encourage patients to get moving. Madison stressed that patients should aim for a minimum of 30 minutes of physical activity 5 days a week. Harris enacted the 20-8-2 method, which has patients sit for 20 minutes, stand for 8 minutes, and then walk for 2 minutes.
The common cold may be considered a mild illness, but the runny nose, congestion, sneezing, cough, sore throat, headache, and other symptoms that come along with it can make people feel miserable. OTC products to treat upper respiratory infections are not a cure; at best, they provide temporary symptom relief. And yet, US consumers, desperate for reprieve from cold-related discomfort, spent more than $9 million last year on these products, according to the Consumer Healthcare Products Association.  

Pharmacists play an important role in helping patients choose the appropriate OTC product based on patient characteristics and specific cold symptoms.

**INGREDIENT REVIEW**

Although a plethora of OTC cough and cold medications are on pharmacy shelves, many of them are very similar. Most oral cold medications contain a combination of some or all of the following active ingredients:

- Acetaminophen for relief of fever, sore throat, headache, and body aches
- Decongestant phenylephrine for the relief of nasal congestion and runny nose
- A first-generation antihistamine such as diphenhydramine, pheniramine, chlorpheniramine, or brompheniramine to reduce postnasal drip and help with sleep
- Cough suppressant dextromethorphan
- Expectorant guaifenesin, which thins mucous secretions in respiratory passages so they can more easily be coughed up

Various products are available in tablet and/or syrup form. Some products, such as the Theraflu line, are available as packets of powder to be mixed into a hot drink—an added benefit because hydration, particularly with hot liquids, helps relieve cold symptoms. Nasal sprays are also an option; some nasal sprays contain decongestants such as oxymetazoline and phenylephrine, whereas saline nasal sprays serve to simply moisten the nasal passages to reduce irritation.

**CUSTOMIZED COMBINATIONS**

Although most combination drugs contain the same basic active ingredients, the number of different formulations on the shelf can be dizzying. Various brand names such as Mucinex, Robitussin, and DayQuil/NyQuil each include several different products for relief of different symptoms. Descriptors can include “cough and cold,” “cough and chest congestion”—sometimes with the word “severe” thrown in for good measure. Many of these are available in daytime and nighttime formulations, which are often packaged together in 1 box.

Mainstay ingredients for daytime cold and flu formulations are usually acetaminophen for fever and pain, phenylephrine for congestion, dextromethorphan for cough suppression, and guaifenesin for loosening secretions. Nighttime formulations for cold and flu typically omit guaifenesin, which can increase coughing, replacing it with dextromethorphan to suppress the cough or an antihistamine to promote drowsiness.

But never make assumptions about what’s in a particular product—the active ingredient or its dosage. For instance, although most combination products contain 325 mg of acetaminophen, some contain 650 mg. Dosages of dextromethorphan and guaifenesin also vary among products. Always check the label to be sure.

**Never make assumptions about what’s in a particular product—the active ingredient or its dosage.**

**Pediatric Considerations**

Although young children are notorious for frequently acquiring colds, they are not always the best candidates for treatment with OTC cold medicines. The FDA states that OTC cold medicines containing decongestants or antihistamines should not be used for children under aged 2 years, as they can cause serious adverse
effects (AEs). The American Academy of Pediatrics (AAP) states that OTC cold medications should not be used in children under aged 4 years due to the risk of dangerous AEs; research has shown little benefit in children under aged 6 years.

Various products are designed for children, and most state on the packaging that they are for children aged 6 years and older. Children aged 12 years of age should not take adult formulations of cough and cold medications, as the dosages may be inappropriate for them.

Caution parents buying pediatric products to keep them out of children's reach, as accidental, unsupervised ingestion is a leading cause of AEs with these drugs.

For children who should not or prefer not to take OTC medications, the AAP recommends using cool mist humidifiers and administering saline nose drops, with a nasal aspirator for infants. Mentholated rubs can help soothe nighttime coughs, and single-ingredient acetaminophen or ibuprofen can be used for fever. There is evidence of honey providing relief for upper respiratory infections, and it is a safe option for children older than 1 year. Babies under 1 year of age should never be given honey due to risk of infant botulism. The AAP recommends half a teaspoon of honey for children aged 1 to 5 years, 1 teaspoon of honey for children aged 6 to 11 years, and 2 teaspoons of honey for children aged 12 years and older. Parents should be cautioned to brush the children's teeth after taking honey before bedtime.

Precautions and Special Populations

Patients' awareness of what is contained in the OTC combination cold medications they're taking is key to ensuring that they don't accidentally overdose. They should especially be cautioned not to take more than 1 acetaminophen-containing product at a time, as acetaminophen overdose is a leading cause of acute liver failure. Although historically the maximum daily dose of acetaminophen was 4000 mg, the makers of Tylenol have lowered the maximum daily dose of single ingredient Tylenol to 3000 mg/day to promote safe use of acetaminophen products.

Since systemic and nasal decongestants work by causing vasoconstriction, they can worsen conditions such as hypertension, glaucoma, and benign prostatic hyperplasia. Patients with these conditions should be directed to formulations labeled “HBP” for high blood pressure or any other products that do not include decongestants.

Special care should be taken for patients taking monoamine oxidase (MAO) inhibitors, as they interact with several components of cough and cold medications. The use of decongestants with MAO inhibitors can cause hypertensive crisis, and dextromethorphan with MAO inhibitors can cause serotonin syndrome.

Patients should be reminded that nighttime formulations containing antihistamines cause drowsiness, so they should only be taken at bedtime—not before driving a vehicle or operating dangerous machinery.

The Importance of Reading Labels

Because there is so much variability between products, reading labels for cough and cold medications is essential to making proper patient-specific recommendations. For example, while Coricidin HBP and DayQuil HBP are similar in that neither contain decongestants, they do not contain the same ingredients; Coricidin HBP Cold & Flu contains acetaminophen and chlorpheniramine, whereas Dayquill HBP Cold & Flu contains acetaminophen and dextromethorphan.

Suffixes can be confusing. Although HBP in a drug name indicates that it is safe for patients with high blood pressure, the DM in some Robitussin products does not indicate that they are formulated for patients with diabetes mellitus. Instead, the DM in those products indicates that they contain dextromethorphan. Patients with diabetes should be directed to cough formulations that do not contain glucose, such as Diabetic Tussin. And the CF in other Robitussin products stands for cough/cold formulation, although those products also contain dextromethorphan.

Careful consideration may sometimes lead to the conclusion that patients might be better off with a single ingredient drug, such as acetaminophen, ibuprofen, or a second-generation antihistamine.

For references, visit drugtopics.com.

Is It a Cold or COVID-19?

In 2020, when a patient comes in to the pharmacy for help selecting a cold medicine, an important question is: Is it really a cold, or could it be coronavirus disease 2019 (COVID-19)?

The answer is not always simple. There are many overlapping symptoms between the 2 infections, including congestion, sore throat, and cough. COVID-19 symptoms that are not common in colds are high fever, chills, shortness of breath, diarrhea, and other gastrointestinal symptoms, and loss of taste or smell.

Pharmacists can also ask patients the following questions to determine their risk of being infected with COVID-19:

- Have you recently attended a large gathering without masks and social distancing?
- Have you been closer than 6 feet to someone with COVID-19 for more than 15 minutes in the past 2 weeks?

In cases with reason to suspect COVID-19 infection, patients should be advised to contact their medical providers to determine whether COVID-19 testing is recommended.
The Best of the Best Pharmacy Awards—sponsored by SingleCare—honor exceptional pharmacists, pharmacy technicians, and pharmacies in communities across the United States.

From thousands of nominations and stories, we have recognized the places and people who go above and beyond.

Congratulations to this year’s winners!
BEST PHARMACIST
Palmira Khalil
Goose Creek, SC

BEST PHARMACY TECH
Hector Torres
Plant City, FL

LIFETIME ACHIEVEMENT AWARD
Elisa Avila
Corpus Christi, TX

BEST PHARMACY FOR EDUCATION
Walgreens #6365
Richmond, VA

BEST PHARMACY DUO
Jesse Pena and Joseph Pena
San Antonio, TX

BEST PHARMACY MENTOR
Meredith Mead
Exeter, PA

COVID CARES PHARMACIST
Sammy Yafai
Auburndale, NY

MOST INFLUENTIAL PHARMACIST
Lisa King
Scottsdale, AZ

MOST CREATIVE PHARMACIST
Alaine Knecht
Baton Rouge, LA

BEST UP-AND-COMING PHARMACIST
Cosmacelenia Hernandez
San Antonio, TX

MOST EMPATHETIC PHARMACY TECH
Katherine Romer
Covington, GA

BEST PHARMACY TECH FOR SERVICE
Sabine Sell
Columbia, SC

See more winners and read their stories at pharmacyawards.com
October is Breast Cancer Awareness Month, and it is important to educate patients about early detection, treatment, and pain management strategies for the second-most-common cancer in women in the US.1,2

Current breast cancer treatment strategies include surgery, radiation, chemotherapy, hormone therapy, and targeted therapy.3 Adding targeted therapies to hormone therapy is a new strategy for advanced or metastatic hormone receptor–positive breast cancer to extend time until chemotherapy and prolong survival.3 Various early detection and treatment research programs are underway to develop enhanced technologies and novel therapies for breast cancer.3 Unfortunately, approximately 70% to 90% of individuals with metastatic breast cancer experience chronic pain.4 Breast cancer pain may be caused by the disease or result from surgery and treatments.4 Pharmacists can play an important role in breast cancer pain management through pharmacological therapy and integrative strategies.

PHARMACOTHERAPY

One systematic review revealed the following posttreatment results for prevalence of persistent pain in patients with breast cancer: postsurgery (29.8%), postradiation (27.3%), and postcombination therapy (21.8%).5 The National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology for Adult Cancer Pain recommend the following “5 As” of outcomes for pain management goals:6

1. Analgesia: Optimize analgesia.
3. Adverse effects (AEs): Minimize AEs.
5. Affect: Understand relationship between pain and mood.

Different types of pain include chronic, acute, and breakthrough (sudden increase in pain even while receiving pain medication). An interdisciplinary approach can help ensure patients are appropriately managed.6

NONOPIOID THERAPY

Patients experiencing mild pain should first receive nonopioids such as acetaminophen or nonsteroidal anti-inflammatory drugs (NSAIDs).6 It is important to educate patients receiving prescription opioids with acetaminophen to avoid taking any OTC products with the same active ingredient to prevent liver toxicity. Individuals should take the lowest effective dose of NSAIDs (eg, ibuprofen, naproxen) for the shortest duration, as many oncology patients may be at high risk for renal, gastrointestinal, cardiac, and bleeding AEs.6 Radiation therapy usually affects the skin, which can be similar to a severe sunburn resulting in redness, tenderness, blisters, and peeling.7

“It is important to educate patients receiving prescription opioids with acetaminophen to avoid taking any OTC products with the same active ingredient to prevent liver toxicity.”
Patients should bathe and shower daily using warm water and a mild unscented soap, rinse the skin well, and pat with a dry, soft towel. Patients should use moisturizers when starting treatment to minimize any skin reactions and should select ones without fragrances or lanolin. Supplemental doses of analgesics should be given prior to procedures to minimize pain. Anxiolytics such as midazolam, lorazepam, or alprazolam can be given 30 to 60 minutes before a procedure to manage anxiety symptoms. Patients should be counseled to avoid driving or operating machinery when taking these medications.

**Opioid Therapy**

Individuals experiencing moderate-to-severe pain can receive opioid therapy for breast cancer pain, which should be initiated at the lowest effective dose that controls pain with the fewest AEs. Patients who are opioid naïve experiencing pain intensity greater than or equal to 4 or less than 4 but whose pain is not being adequately controlled can be started on a dose of 5 to 15 mg of oral morphine sulfate or 2 to 5 mg of intravenous morphine sulfate or equivalent. Opioid options include oxycodone immediate release, hydrocodone with acetaminophen, and hydromorphone. If 4 or more doses are needed per day, then a long-acting opioid can be added. Opioid dose reductions (reduce by 10%-20%) can be considered for patients that rarely need breakthrough medication, have managed an acute pain event, or experienced pain control through a nonopioid therapy.

Gabapentin and pregabalin (Lyrica) are common anticonvulsants used as adjuvant analgesics. Gabapentin can reduce mucositis pain in patients receiving concomitant radiotherapy and chemotherapy. Patients with renal insufficiency should receive dose adjustments for gabapentin and pregabalin. Corticosteroids (eg, dexamethasone) can also be used as adjuvant agents to reduce swelling and manage pain. These medications should generally be taken in the morning to prevent nighttime insomnia. Topical agents (eg, lidocaine patch) can be applied daily as an adjuvant analgesic.

**Nonpharmacologic Options**

Evidence suggests that in addition to pharmacologic interventions, integrative therapies can also be used for pain management, including physical therapy, exercise, heat and/or ice application, psychological services, massage, meditation, and yoga. Applying heat can help relieve muscle soreness, whereas cold can decrease pain by numbing the area. It is important to avoid applying cold or heat over any area where patients are receiving radiation therapy and for 6 months after treatment has ended. Physical therapy is especially important for patients undergoing radiation therapy for range-of-motion arm exercises to prevent scar tissue from forming. And because anxiety and depression can worsen pain, joining an emotional support group may help alleviate these symptoms.

For references, visit drugtopics.com.
**Indication**
SHINGRIX is a vaccine indicated for prevention of herpes zoster (shingles) in adults aged 50 years and older. SHINGRIX is not indicated for prevention of primary varicella infection (chickenpox).

**Important Safety Information**
SHINGRIX is contraindicated in anyone with a history of a severe allergic reaction (eg, anaphylaxis) to any component of the vaccine or after a previous dose of SHINGRIX.

- Review immunization history for possible vaccine sensitivity and previous vaccination-related adverse reactions. Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of SHINGRIX.
- Solicited local adverse reactions in subjects aged 50 years and older were pain (78.0%), redness (38.1%), and swelling (25.9%).
If your patients have already come into your pharmacy for their first dose of SHINGRIX, they’re not done. SHINGRIX is a 2-dose series with the second dose given anytime between 2 to 6 months after the first.¹ That’s important: the efficacy of SHINGRIX was demonstrated in clinical trials when it was administered as a 2-dose series.² They count on you to administer dose #2.

**MANAGE EXPECTATIONS:**
**DISCUSS ADVERSE REACTIONS**

Patients may experience adverse reactions. The key: throughout the vaccination process, make sure patients know what to expect. The most common side effects observed in clinical trials were pain, redness, and swelling at the injection site, myalgia, fatigue, headache, shivering, fever, and gastrointestinal symptoms.¹

**GIVE YOUR PATIENTS THE NUDGE THEY NEED**

With the busy lives your patients lead, they can occasionally miss their second dose. Reminders can help. So if your pharmacy doesn’t have a reminder system in place, encourage patients to sign up for calls, emails, or text messages at SHINGRIXreminder.com.

Get additional patient talking points at SHINGRIXtips.com

---

**Important Safety Information (cont’d)**

- Solicited general adverse reactions in subjects aged 50 years and older were myalgia (44.7%), fatigue (44.5%), headache (37.7%), shivering (26.8%), fever (20.5%), and gastrointestinal symptoms (17.3%)
- SHINGRIX was not studied in pregnant or lactating women, and it is unknown if it is excreted in human milk. Therefore, it cannot be established whether there is vaccine-associated risk with SHINGRIX in pregnant women or if there are effects on breastfed infants or milk production/excretion
- Vaccination with SHINGRIX may not result in protection of all vaccine recipients

Please see Brief Summary of Prescribing Information for SHINGRIX on the following pages.

Reference: 1. Prescribing Information for SHINGRIX.

Trademarks are owned by or licensed to the GSK group of companies.

©2020 GSK or licensor. SGX/RNA200019 August 2020
Produced in USA.
SHINGRIX (Zoster Vaccine Recombinant, Adjuvanted)

The following is a brief summary only; see full prescribing information for complete product information.

1 INDICATIONS AND USAGE

SHINGRIX is a vaccine indicated for prevention of herpes zoster (shingles) in adults aged 50 years and older.

Limitations of Use:

SHINGRIX is not indicated for prevention of primary varicella infection (chickenpox).

2 DOSAGE AND ADMINISTRATION

2.1 Administration Instructions

For intramuscular injection only.

After reconstitution, administer SHINGRIX immediately or store refrigerated between 2° and 8°C (36° and 46°F) and use within 6 hours. Discard reconstituted vaccine if not used within 6 hours.

2.3 Dose and Schedule

Two doses (0.5 mL each) administered intramuscularly according to the following schedule: A first dose at Month 0 followed by a second dose administered anytime between 2 and 6 months later.

4 CONTRAINDICATIONS

Do not administer SHINGRIX to anyone with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine or after a previous dose of SHINGRIX [see Description (11) of full prescribing information].

5 WARNINGS AND PRECAUTIONS

5.1 Preventing and Managing Allergic Vaccine Reactions

Prior to administration, the healthcare provider should review the immunization history for possible vaccine sensitivity and previous vaccination-related adverse reactions. Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of SHINGRIX.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reactions rates observed in the clinical trials of a vaccine cannot be directly compared with rates in the clinical trials of another vaccine and may not reflect the rates observed in practice. There is the possibility that broad use of SHINGRIX could reveal adverse reactions not observed in clinical trials.

Overall, 17,041 adults aged 50 years and older received at least 1 dose of SHINGRIX in 17 clinical studies.

The safety of SHINGRIX was evaluated by pooling data from 2 phase-3 controlled clinical studies (Studies 1 and 2) involving 29,305 subjects aged 50 years and older who received at least 1 dose of SHINGRIX (n = 14,645) or saline placebo (n = 14,660) administered according to a 0- and 2-month schedule. At the time of vaccination, the mean age of the population was 69 years; 7,286 (24.9%) subjects were aged 50 to 59 years, 4,488 (15.3%) subjects were aged 60 to 69 years, and 17,511 (59.8%) subjects were aged 70 years and older. Both studies were conducted in North America, Latin America, Europe, Asia, and Australia. In the overall population, the majority of subjects were white (74.3%), followed by Asian (18.3%), black (1.4%), and other racial/ethnic groups (6.0%); 58% were female.

Solicited Adverse Reactions

In Studies 1 and 2, data on solicited local and general adverse events were collected using standardized diary cards for 7 days following each vaccine dose or placebo (i.e., day of vaccination and the next 6 days) in a subset of subjects (n = 4,886 receiving SHINGRIX, n = 4,881 receiving placebo with at least 1 documented dose). Across both studies, the percentages of subjects aged 50 years and older reporting each solicited local adverse reaction and each solicited general adverse event following administration of SHINGRIX (both doses combined) were pain (78.0%), redness (38.1%), and swelling (25.9%); and myalgia (44.7%), fatigue (44.5%), headache (37.7%), shivering (26.8%), fever (20.5%), and gastrointestinal symptoms (17.3%), respectively.

6.2 Postmarketing Experience

The following adverse reactions have been identified during post-licensure use of SHINGRIX. These adverse reactions are not necessarily caused by the vaccine and are not necessarily a result of immunization. SHINGRIX could reveal adverse reactions not observed in clinical trials.

6.3 Laboratory Abnormalities

No clinically meaningful differences in laboratory test results were observed in clinical studies compared with placebo recipients.

7 USE IN SPECIFIC POPULATIONS

7.1 Concomitant Vaccine Administration

The administration of SHINGRIX is not recommended in the same syringe or at the same injection site as any other vaccine. If a second vaccine is to be administered, it should be administered at another injection site.

7.2 Immunosuppressive Therapies

Immunosuppressive therapies may reduce the effectiveness of SHINGRIX. Caution is recommended in patients who are immunosuppressed.

7.3 Pregnancy

Although animal studies have not been performed, the manufacturer recommends that SHINGRIX not be used during pregnancy.

7.4 Nursing Mothers

It is unknown whether SHINGRIX is excreted in human milk. Because many vaccines are excreted in human milk, caution should be exercised when SHINGRIX is administered to a nursing woman.

8 ADVERSE REACTIONS

The reported frequencies of specific solicited local adverse reactions and general adverse events (overall per subject), by age group, from the 2 studies are presented in Table 1.

Table 1. Percentage of Subjects with Solicited Local Adverse Reactions and General Adverse Events within 7 Daysa of Vaccination in Adults Aged 50 to 59 Years, 60 to 69 Years, and 70 Years and Olderb (Total Vaccinated Cohort with 7-Day Diary Card)

<table>
<thead>
<tr>
<th>Age Group</th>
<th>SHINGRIX %</th>
<th>Placebo%</th>
<th>SHINGRIX %</th>
<th>Placebo%</th>
<th>SHINGRIX %</th>
<th>Placebo%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local Adverse Reactions</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aged 50-59 Years</td>
<td>n=1,315</td>
<td>n=1,312</td>
<td>n=1,311</td>
<td>n=1,305</td>
<td>n=2,256</td>
<td>n=2,263</td>
</tr>
<tr>
<td>Pain</td>
<td>88.4</td>
<td>14.4</td>
<td>82.8</td>
<td>11.1</td>
<td>69.2</td>
<td>8.8</td>
</tr>
<tr>
<td>Pain, Grade 3</td>
<td>10.3</td>
<td>0.5</td>
<td>6.9</td>
<td>0.5</td>
<td>4.0</td>
<td>0.2</td>
</tr>
<tr>
<td>Redness</td>
<td>38.7</td>
<td>1.2</td>
<td>38.4</td>
<td>1.6</td>
<td>37.7</td>
<td>1.2</td>
</tr>
<tr>
<td>Redness, &gt;100 mm</td>
<td>2.8</td>
<td>0.0</td>
<td>2.6</td>
<td>0.0</td>
<td>3.1</td>
<td>0.0</td>
</tr>
<tr>
<td>Swelling</td>
<td>30.5</td>
<td>0.8</td>
<td>26.5</td>
<td>1.0</td>
<td>23.0</td>
<td>1.1</td>
</tr>
<tr>
<td>Swelling, &gt;100 mm</td>
<td>1.1</td>
<td>0.0</td>
<td>0.5</td>
<td>0.0</td>
<td>1.3</td>
<td>0.0</td>
</tr>
<tr>
<td>General Adverse Events</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aged 50-59 Years</td>
<td>n=1,315</td>
<td>n=1,312</td>
<td>n=1,309</td>
<td>n=1,305</td>
<td>n=2,252</td>
<td>n=2,264</td>
</tr>
<tr>
<td>Myalgia</td>
<td>56.9</td>
<td>15.2</td>
<td>49.0</td>
<td>11.2</td>
<td>35.1</td>
<td>9.9</td>
</tr>
<tr>
<td>Myalgia, Grade 3</td>
<td>8.9</td>
<td>0.9</td>
<td>5.3</td>
<td>0.8</td>
<td>2.8</td>
<td>0.4</td>
</tr>
<tr>
<td>Fatigue</td>
<td>57.0</td>
<td>19.8</td>
<td>45.7</td>
<td>16.8</td>
<td>36.6</td>
<td>14.4</td>
</tr>
<tr>
<td>Fatigue, Grade 3</td>
<td>8.5</td>
<td>1.8</td>
<td>5.0</td>
<td>0.8</td>
<td>3.5</td>
<td>0.8</td>
</tr>
<tr>
<td>Headache</td>
<td>50.6</td>
<td>21.6</td>
<td>39.6</td>
<td>15.6</td>
<td>29.0</td>
<td>11.8</td>
</tr>
<tr>
<td>Headache, Grade 3</td>
<td>6.0</td>
<td>1.7</td>
<td>3.7</td>
<td>0.2</td>
<td>1.5</td>
<td>0.4</td>
</tr>
<tr>
<td>Shivering</td>
<td>35.8</td>
<td>7.4</td>
<td>30.3</td>
<td>5.7</td>
<td>19.5</td>
<td>4.9</td>
</tr>
<tr>
<td>Shivering, Grade 3</td>
<td>6.8</td>
<td>0.2</td>
<td>4.5</td>
<td>0.3</td>
<td>2.2</td>
<td>0.3</td>
</tr>
<tr>
<td>Fever</td>
<td>27.8</td>
<td>3.0</td>
<td>23.9</td>
<td>3.4</td>
<td>14.3</td>
<td>2.7</td>
</tr>
<tr>
<td>Fever, Grade 3</td>
<td>0.4</td>
<td>0.2</td>
<td>0.5</td>
<td>0.2</td>
<td>0.1</td>
<td>0.1</td>
</tr>
<tr>
<td>GI</td>
<td>24.3</td>
<td>10.7</td>
<td>16.7</td>
<td>8.7</td>
<td>13.5</td>
<td>7.6</td>
</tr>
<tr>
<td>GI, Grade 3</td>
<td>2.1</td>
<td>0.7</td>
<td>0.9</td>
<td>0.6</td>
<td>1.2</td>
<td>0.4</td>
</tr>
</tbody>
</table>

Total vaccinated cohort for safety included all subjects with at least 1 documented dose (n).

a 7 days included day of vaccination and the subsequent 6 days.

b Data for subjects aged 50 to 59 years and 60 to 69 years are based on Study 1. Data for subjects 70 years and older are based on pooled data from Study 1: NCT01165177 and Study 2: NCT01165229.

c Placebo was a saline solution.

d Grade 3 pain: Defined as significant pain at rest; prevents normal everyday activities.

e Grade 3 myalgia, fatigue, headache, shivering, GI: Defined as preventing normal activity.

f Fever defined as ≥37.5°C/99.5°F for oral, axillary, or tympanic route, or ≥38°C/100.4°F for rectal route; Grade 3 fever defined as ≥39.0°C/102.2°F.

g GI = Gastrointestinal symptoms including nausea, vomiting, diarrhea, and/or abdominal pain.

(continued on next page)
The incidence of solicited local and general symptoms was lower in subjects aged 70 years and older compared with those aged 50 to 69 years. The majority of solicited local adverse reactions and general adverse events seen with SHINGRIX had a median duration of 2 to 3 days.

There were no differences in the proportions of subjects reporting any or Grade 3 solicited local reactions between Dose 1 and Dose 2. Headache and shivering were reported more frequently by subjects after Dose 2 (28.2% and 21.4%, respectively) compared with Dose 1 (24.4% and 13.8%, respectively). Grade 3 solicited general adverse events (headache, shivering, myalgia, and fatigue) were reported more frequently by subjects after Dose 2 (2.3%, 3.1%, 3.6%, and 3.5%, respectively) compared with Dose 1 (1.4%, 1.4%, 2.3%, and 2.4%, respectively).

Unsolicited Adverse Events

Unsolicited adverse events that occurred within 30 days following each vaccination (Day 0 to 29) were recorded on a diary card by all subjects. In the 2 studies, unsolicited adverse events occurring within 30 days of vaccination were reported in 50.5% and 32.0% of subjects who received SHINGRIX (n = 14,645) and placebo (n = 14,660), respectively (Total Vaccinated Cohort). Unsolicited adverse events that occurred in ≥1% of recipients of SHINGRIX and at a rate at least 1.5-fold higher than placebo included chills (3.5% versus 0.2%), injection site pruritus (2.2% versus 0.2%), malaise (1.7% versus 0.3%), arthralgia (1.7% versus 1.2%), nausea (1.4% versus 0.5%), and dizziness (1.2% versus 0.8%).

Gout (including gouty arthritis) was reported by 0.18% (n = 27) versus 0.03% (n = 8) of subjects who received SHINGRIX and placebo, respectively, within 30 days of vaccination; available information is insufficient to determine a causal relationship with SHINGRIX.

Serious Adverse Events (SAEs)

In the 2 studies, SAEs were reported at similar rates in subjects who received SHINGRIX (2.3%) and placebo (2.2%) from the first administration up to 30 days post last vaccination. SAEs were reported for 10.1% of subjects who received SHINGRIX and for 10.4% of subjects who received placebo from the first administered dose up to 1 year post last vaccination. One subject (<0.01%) reported lymphadenitis and 1 subject (<0.01%) reported fever greater than 39°C; there was a basis for a causal relationship with SHINGRIX.

Optic ischemic neuropathy was reported in 3 subjects (0.02%) who received SHINGRIX (all within 50 days after vaccination) and 0 subjects who received placebo. Available information is insufficient to determine a causal relationship with SHINGRIX.

Deaths

From the first administered dose up to 30 days post last vaccination, deaths were reported for 0.04% of subjects who received SHINGRIX and 0.05% of subjects who received placebo in the 2 studies. From the first administered dose up to 1 year post last vaccination, deaths were reported for 0.8% of subjects who received SHINGRIX and for 0.9% of subjects who received placebo. Causes of death among subjects were consistent with those generally reported in adult and elderly populations.

Potential Immune-Mediated Diseases

In the 2 studies, new onset potential immune-mediated diseases (pIMDs) or exacerbation of existing pIMDs were reported for 0.6% of subjects who received SHINGRIX and 0.7% of subjects who received placebo from the first administered dose up to 1 year post last vaccination. The most frequently reported pIMDs occurred with comparable frequencies in the group receiving SHINGRIX and the placebo group.

Dosing Schedule

In an open-label clinical study, 238 subjects 50 years and older received SHINGRIX as a 0- and 2-month or 0- and 6-month schedule. The safety profile of SHINGRIX was similar when administered according to a 0- and 2-month or 0- and 6-month schedule and was consistent with that observed in Studies 1 and 2.

6.2 Postmarketing Experience

The following adverse reactions have been identified during postapproval use of SHINGRIX. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to the vaccine.

General Disorders and Administration Site Conditions

Decreased mobility of the injected arm which may persist for 1 or more weeks.

Immune System Disorders

Hypersensitivity reactions, including angioedema, rash, and urticaria.

7 DRUG INTERACTIONS

7.1 Concomitant Vaccine Administration

For concomitant administration of SHINGRIX with inactivated influenza vaccine [see Clinical Studies (14.5) of full prescribing information].

7.2 Immunosuppressive Therapies

Immunosuppressive therapies may reduce the effectiveness of SHINGRIX.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

There are no available human data to establish whether there is vaccine-associated risk with SHINGRIX in pregnant women [see Use in Specific Populations (8.1) of full prescribing information].

8.2 Lactation

It is not known whether SHINGRIX is excreted in human milk. Data are not available to assess the effects of SHINGRIX on the breastfed infant or on milk production/excretion [see Use in Specific Populations (8.2) of full prescribing information].

8.5 Geriatric Use

Of the total number of subjects who received at least 1 dose of SHINGRIX in the 2 efficacy trials (n = 14,645), 2,243 (15.3%) were aged 60 to 69 years, 6,837 (46.7%) were aged 70 to 79 years, and 1,921 (13.1%) were 80 years and older. There were no clinically meaningful differences in efficacy across the age groups or between these subjects and younger subjects [see Clinical Studies (14.1, 14.2, 14.3) of full prescribing information].

The frequencies of solicited local and general adverse events in subjects aged 70 years and older were lower than in younger adults (aged 50 through 69 years) [see Adverse Reactions (6.1)].

17 PATIENT COUNSELING INFORMATION

• Inform patients of the potential benefits and risks of immunization with SHINGRIX and of the importance of completing the 2-dose immunization series according to the schedule.

• Inform patients about the potential for adverse reactions that have been temporally associated with administration of SHINGRIX.

• Provide the Vaccine Information Statements, which are available free of charge at the Centers for Disease Control and Prevention (CDC) website (www.cdc.gov/vaccines).

Storage:

Store vials of Lyophilized gE Antigen and Adjuvant Suspension Components refrigerated between 2° and 8°C (36°F and 46°F). Protect vials from light. Do not freeze. Discard if the vials have been frozen.

Trademarks are owned by or licensed to the GSK group of companies.

Manufactured by GlaxoSmithKline Biologicals Rixensart, Belgium, U.S. License 1617, and Distributed by GlaxoSmithKline Research Triangle Park, NC 27709

©2019 GSK group of companies or its licensor. October 2019 SHX:4BRS

©2020 GSK or licensor.

SGXJRNA200019 August 2020

Produced in USA.
Good Neighbor Pharmacy
State of the Union

Organization discusses how it is advocating and supporting community pharmacies to grow and innovate beyond their traditional model. By Jennifer Barrett

On September 15, 2020, AmerisourceBergen and Good Neighbor Pharmacy (GNP) kicked off the first virtual ThoughtSpot, GNP’s annual independent community pharmacy conference and trade show.

In an interview with Drug Topics®, Rich Tremonte, executive vice president and president of Community & Specialty Pharmacy at AmerisourceBergen and Brian Nightengale, PhD, RPh, president of GNP provided an update on how the organizations are helping independent pharmacies thrive during this time and key focus areas for the year ahead.

The Value of Good Neighbor Pharmacy

Now more than ever, patients are seeking local, personalized, and trusted care. The coronavirus disease 2019 (COVID-19) pandemic has forced many pharmacies to adapt to meet the needs of the community. With new challenges at the forefront, GNP is committed to supporting community pharmacists on the front lines.

Speaking to the value of GNP to its customers, Tremonte cited the JD Power 2020 US Pharmacy Study, in which GNP ranked No. 1 in Customer Satisfaction with Chain Drug Store Pharmacies for the fourth consecutive year. This achievement also marks the ninth time GNP has scored the top spot in the past 11 years. Now in its 12th year, the US Pharmacy Study measures customer satisfaction with brick-and-mortar and mail-order pharmacies. GNP ranked No. 1 in all 5 factors: pharmacist, nonpharmacist staff, store, cost competitiveness, and prescription ordering and filling process.1

The study revealed that pharmacy operators are positioning and embracing themselves as hubs of consumer health care, driving higher overall satisfaction, and increased spending as they use more health and wellness-oriented services.1 In the wake of COVID-19, pharmacists are finding new ways to engage with patients, and GNP continues to support pharmacies in the ever-evolving health care climate as they look to diversify their businesses.

“At Good Neighbor Pharmacy we always have a finger on the pulse of the industry and are investing in services and solutions to help independent pharmacies thrive—not just in today’s environment, but in the future, too. Many of the trends and patient needs we predicted and subsequently invested in over the last few years have proven to be critical in the fight against COVID-19,” said Nightengale.

For smaller independent pharmacies especially, it can be difficult to balance providing the high-touch, personalized patient care that community pharmacies are known for with all the other facets of operating a business. Nightengale pointed to GNP’s Elevate Provider Network as an example of how the organization can help.

“Certainly one of our biggest values that we provide is through our Elevate Provider Network, where we represent thousands of these independent pharmacies in negotiations with [pharmacy benefit managers] and payers,” he explained. Other areas of support include providing digital marketing guidance and front-end expertise. With GNP, independent pharmacies have access to the services and solutions that help them take advantage of these growth areas.

COVID-19 Support

Tremonte noted that AmerisourceBergen has remained committed to the safety and security of the supply chain during the pandemic by working with manufacturers to stay on top of supply chain disruptions and shortages and by making ongoing investments in its distribution services and business continuity planning capabilities.

Tremonte explained how these investments have proven successful during the pandemic.

“In the beginning of the pandemic, we actually had to close one of our distribution centers due to confirmed-cases of COVID-19 in the facility,” Tremonte said. “Putting our people first and shutting the facility down was an easy decision. What also gave us the confidence was knowing that we had made substantial investments in business continuities across our network and through these investments, we were able to send orders to other distribution centers so our pharmacies were able to continue to get next-day deliveries.”

AmerisourceBergen has also hosted 8 customer town halls, in which company officials speak openly with customers to maintain a transparent...
exchange of information. Early in the pandemic, GNP deployed a COVID-19 resource center for its pharmacies on its website.  

“If you’re a pharmacy, we really give you a 1-stop shop [on] our website [to make] it easy to get all the important information you need [including] updates because there are so many changing guidelines,” Tremonte said.

Tremonte mentioned the Fearless Pharmacy campaign, launched by AmerisourceBergen and GNP, which features independent pharmacies going above and beyond for their communities. These inspiring stories have been compiled and showcased on GNP’s website.

**A Focus on Digital**

If anything has demonstrated the need and value of expanded access to community-based care, it’s been COVID-19. Knowing the challenges that COVID-19 has posed for patients, Nightengale also discussed how GNP can help pharmacies commit to patients in a meaningful way.

“(COVID-19) certainly has highlighted the need to have an omnichannel approach,” Nightengale said. “Digital expansion is something we will continue to invest in, [and] it’s certainly something we’re going to continue to advise and support our stores in adopting.”

As consumers’ openness to telehealth continues to increase amid the pandemic, local pharmacies will need to move in that direction to provide the same level of care through a multichannel approach.

GNP also works with pharmacies to develop multichannel digital marketing solutions designed to reach patients online through social media, mobile technologies that allow patients to manage prescriptions from home, e-commerce platforms, and more.

“We are committed to working with our teams and members to expand our capabilities and broaden their horizons in the omnichannel approach,” Nightengale said.

**Expansion of Clinical Services**

With more restricted avenues for access to care, community pharmacies have become even more vital to serving marketplace needs—making it an important time to expand their clinical service offerings.

Recently the US Department of Health and Human Services (HHS), through the Assistant Secretary for Health, issued guidance under the Public Readiness and Emergency Preparedness Act to expand access to safe and effective COVID-19 vaccines when they are made available. This guidance authorizes state-licensed pharmacists to order and administer COVID-19 vaccinations to persons aged 3 or older, subject to certain requirements. With this move in the right direction, it allows pharmacists to provide added value and benefit to the health care market as a whole by opening up access to highly trained community practitioners.

And with a growing shortage of primary care providers, especially in rural and underserved areas, community pharmacists are well-positioned to fill health care gaps.

This new authorization preempts any state and local laws that prohibit or effectively prohibits those who satisfy these requirements from ordering or administering COVID-19 vaccines as set forth above. However, state and federal regulations and payment restrictions hold pharmacists back from practicing at the top of their license beyond COVID-19.

GNP continues to focus on leading advocacy efforts at the federal and state levels, targeting areas of payment reform and expanded scope of practice. Other valuable services such as expanded immunization services and point-of-care testing in the pharmacy can provide a huge benefit to the health care system.

“I think coming out of COVID-19, the profession is united in really pushing harder for the pharmacist’s ability to provide point-of-care testing and screening and to make appropriate therapeutic decisions from that,” Nightengale said.

**Looking Ahead**

Nightengale discussed key areas of focus for GNP in the year ahead.

“Where we’re focused in the year ahead is to continue the great momentum that we’ve had in expanding the utilization of our digital marketing programs,” he said. Continuing to invest in digital expansion is going to be key in helping independents grow in the ever-evolving market, especially to attract and retain a new generation of customers.”

As pharmacies continue to pivot their services to adapt, supporting business expansion beyond the traditional dispensing will be crucial to success.

“We partner and work closely with organizations like the Community Pharmacy Enhanced Services Network, CPESN,” Nightengale explained. “We encourage our pharmacies to join networks like that so we can open up contracts and performance-based services for payers that are provided by the pharmacies.”

Nightengale added that GNP also launched a pet meds program and is expanding its hospice solution.

“It falls in line with continuing to advocate and support our pharmacies to grow their business and to innovate beyond their traditional model so that they can participate in the future of health care and what the future of pharmacy looks like,” he concluded.

This article was written in partnership with AmerisourceBergen and Good Neighbor Pharmacy.

For references, visit drugtopics.com.

DrugTopics.com

October 2020

DrugTopics®
October is American Pharmacists Month. This year more than ever, take time to acknowledge the valuable contributions of your pharmacy staff.

By Karen Berger, PharmD

CAREER

Celebrate the Pharmacy Profession

October is American Pharmacists Month. This year more than ever, take time to acknowledge the valuable contributions of your pharmacy staff. 

As a pharmacy manager, my team, both pharmacists and technicians, is the key to our success! I am only one person and can’t possibly meet the needs of a large and diverse patient population.” 

—Trisha Winroth, PharmD

Trisha Winroth, PharmD, pharmacy manager at Walgreens in Lowell, Massachusetts, plans to celebrate her team during the month of October, showing her appreciation with gifts like jewelry, personalized mugs, wine, shopping bags, or water bottles. “As a pharmacy manager, my team, both pharmacists and technicians, is the key to our success! I am only one person and can’t possibly meet the needs of a large and diverse patient population,” she said. “Their daily impact on patient care—from refilling prescriptions to calling doctors or patients [to] helping patients find resources to translating or explaining paperwork for a vaccine— Touches far more lives than I could ever do alone.”

Cara Hoyt, PharmD, a pharmacist at Uptown Pharmacy in Westerville, Ohio, tries to celebrate her team all year round, particularly since October is prime time for flu shots. “October is always a busy month for our pharmacy,” she said. “Between doing vaccinations in house and onsite, we don’t get to celebrate every day. But we try to celebrate our fantastic team all year long! We provide meals, ice cream, and other treats during pharmacists month and [throughout] the year. We want to show our staff we care about them [because] we know we need our whole team to provide the best care.”

The Uptown Pharmacy team also works together to provide value to the community through other clinical services such as point-of-care testing for international normalized ratios, diabetes education, compounding, medication synchronization, a community residency program, and research projects.

In addition, Hoyt is advancing the pharmacy practice through the Community Pharmacy Foundation (CPF) by working on a transition-of-care study in partnership with a local emergency department doctor and home health care agency. “We know that pharmacists can add great value as part of the patient care team,” she said. “Pharmacists can help improve outcomes and reduce adverse effects and hospital readmissions.”

Ashley Abode, PharmD, the clinical services coordinator at Realo Drugs in New Bern, North Carolina, says they celebrate...
their technicians with coffee and treats in October and also year-round. Abode and her team are also hard at work demonstrating the value of pharmacists. For example, her staff provides diabetes education classes and a diabetes prevention program (now held virtually due to COVID-19). “We teach patients about nutrition and physical activity to help prevent diabetes. We have been very successful—about 67% of participants have achieved their weight loss goals,” she said.

Abode has also worked with the CPF on 2 projects, and although the grants are complete, the team is still providing the clinical services. The first project was to demonstrate the value of community pharmacists as part of a care team. To accomplish this, Abode and her team provide offsite medication reviews combined with services offered in the pharmacy, such as adherence packaging. The services have been so successful that referrals are rolling in.

The second project was to show the pharmacy team’s value in home health care. Adobe says that working with home health agencies on medication reviews has been very successful. And the pharmacy team is paid for services. “That is rewarding because providers realize our value,” she said.

Steve “Slava” Malen, PharmD, the pharmacy manager at Crossroads Specialty Pharmacy in Livingston, New Jersey, has something very special planned for the team. “I have the privilege of working at a specialty pharmacy that does compounding and medication-therapy management. We aren’t able to do any of these things without our amazing technicians, so we will have a sushi party to celebrate them,” he said.

Malen also plans to sit down individually with each technician to gain new perspectives on what they would change within the pharmacy. “They are an important part of the pharmacy and deserve to be a part of the pharmacy’s constant evolution.”

Rannon Ching, PharmD, the pharmacist in charge at Tarrytown Pharmacy in Austin, Texas, plans to celebrate American Pharmacists Month by providing a catered lunch for the staff. Ching noted that pharmacists are really on the front lines right now and are making a significant impact. In addition to providing glycated hemoglobin and glucose testing services, Ching and his team have also been busy providing COVID-19 diagnostic testing to patients. “It’s a great resource for our community, great for revenue, and we get same-day results, which makes patients happy,” he explained. So far, the pharmacy has tested 1700 patients for COVID-19.

Ching is also working with CPF to demonstrate how pharmacists can help with transitions of care to impact hospital readmission rates. Ching and other pharmacists meet with the patient to counsel on medications and provide the patient with an updated medication list. They also notify the primary care provider of any medication changes. Due to COVID-19, Ching is working on this project remotely but looks forward to returning to in-person consultations as soon as possible.

“Pharmacies and pharmacists are in a great position to leverage their accessibility, knowledge, and great relationships with patients and health care facilities to provide advanced services beyond just filling prescriptions,” he said. “The patients appreciate it and feel much more confident in their understanding of the plan.”

**Ways to Celebrate American Pharmacists Month**

1. Provide coffee and treats, or a catered meal, for pharmacy staff throughout the month to demonstrate appreciation.

2. Decorate the pharmacy with signs or displays that promote American Pharmacists Month.

3. Use your pharmacy’s social media page to introduce your employees, share brief bios about each staff member, and post pictures highlighting activities in the pharmacy.

4. Give back to the community by offering health screening events or promoting flu vaccinations.

5. Recognize your technicians on Pharmacy Technician Day (October 20) and celebrate their contributions.
Indication for AirDuo RespiClick/Authorized Generic

AirDuo RespiClick is indicated for the treatment of asthma in patients aged 12 years and older. AirDuo RespiClick is only for patients uncontrolled on an inhaled corticosteroid (ICS) or whose disease severity clearly warrants an ICS/Long-acting beta₂-agonist (LABA).

Important Limitation of Use: AirDuo RespiClick is NOT indicated for the relief of acute bronchospasm.

Important Safety Information for AirDuo RespiClick/Authorized Generic

- **Contraindications:** AirDuo RespiClick is contraindicated in:
  - Primary treatment of status asthmaticus or other acute episodes of asthma requiring intensive measures
  - Patients with known severe hypersensitivity to milk proteins or any ingredients of AirDuo RespiClick

Please see additional Important Safety Information and Brief Summary of Full Prescribing Information on the following pages.
Recommended starting dose: 1 inhalation twice daily\(^1\)\(^-\)\(^3\)

<table>
<thead>
<tr>
<th>AirDuo RespiClick</th>
<th>Authorized Generic</th>
<th>ADVAIR DISKUS(^\circledast)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluticasone propionate + Salmeterol</td>
<td>Fluticasone propionate + Salmeterol</td>
<td>Fluticasone propionate + Salmeterol</td>
</tr>
<tr>
<td>Low</td>
<td>55 mcg + 14 mcg</td>
<td>55 mcg + 14 mcg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>100 mcg + 50 mcg</td>
</tr>
<tr>
<td>Medium</td>
<td>113 mcg + 14 mcg</td>
<td>113 mcg + 14 mcg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>250 mcg + 50 mcg</td>
</tr>
<tr>
<td>High</td>
<td>232 mcg + 14 mcg</td>
<td>232 mcg + 14 mcg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>500 mcg + 50 mcg</td>
</tr>
</tbody>
</table>

\(\text{ADV AIR DISKUS}\)\(^\circledast\) is a registered trademark of the GSK group of companies.

Table is intended to show differences in dosing only and should not be construed to imply safety or efficacy similarities or differences.

IMPORTANT SAFETY INFORMATION for AirDuo RespiClick/Authorized Generic (continued)

- **Serious Asthma-Related Events – Hospitalizations, Intubations, Death:** Use of LABA as monotherapy (without ICS) for asthma is associated with an increased risk of asthma-related death. Available data from controlled clinical trials also suggest that use of LABA as monotherapy increases the risk of asthma-related hospitalization in pediatric and adolescent patients. These findings are considered a class effect of LABA monotherapy. When LABA are used in fixed-dose combination with ICS, data from large clinical trials do not show a significant increase in the risk of serious asthma-related events (hospitalizations, intubations, death) compared with ICS alone.

- **Deterioration of Disease and Acute Episodes:** AirDuo RespiClick should not be initiated in patients during rapidly deteriorating or potentially life-threatening episodes of asthma. AirDuo RespiClick is not indicated for the relief of acute bronchospasm. An inhaled, short-acting beta\(_2\)- agonist, not AirDuo RespiClick, should be used to relieve acute symptoms such as shortness of breath.

- **Excessive Use and Use with Other Long acting Beta\(_2\)-Agonists:** AirDuo RespiClick should not be used more often than recommended, at higher doses than recommended, or in conjunction with other medicines containing LABA, as an overdose may result. Clinically significant cardiovascular effects and fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs. Patients using AirDuo RespiClick should not use another medicine containing a LABA (e.g., salmeterol, formoterol fumarate, arformoterol tartrate, indacaterol) for any reason.

Please see additional Important Safety Information throughout and Brief Summary of Full Prescribing Information on the following pages.
**IMPORTANT SAFETY INFORMATION** for AirDuo RespiClick/Authorized Generic (continued)

- **Local Effects of ICS:** Oropharyngeal candidiasis has occurred in patients treated with AirDuo RespiClick. If this occurs, treat with appropriate local or systemic (i.e., oral) antifungal therapy while treatment with AirDuo RespiClick continues, but at times therapy with AirDuo RespiClick may need to be interrupted. Advise the patient to rinse his/her mouth with water without swallowing following inhalation.

- **Immunosuppression:** Patients who use corticosteroids are at risk for potential worsening of existing tuberculosis; fungal, bacterial, viral, or parasitic infections; or ocular herpes simplex. A more serious or even fatal course of chickenpox or measles may occur in susceptible patients. Use with caution in patients with the above because of the potential for worsening of these infections.

- **Transferring Patients from Systemic Corticosteroid Therapy:** Particular care is needed for patients who have been transferred from systemically active corticosteroids to ICS because deaths due to adrenal insufficiency have occurred in patients with asthma during and after transfer from systemic corticosteroids to less systemically available ICS. Taper patients slowly from systemic corticosteroids if transferring to AirDuo RespiClick.

- **Hypercorticism and Adrenal Suppression** may occur with high doses of ICS, including fluticasone propionate, or at the recommended dose in susceptible individuals. If such changes occur, discontinue AirDuo RespiClick slowly.

- **Drug Interactions with Strong Cytochrome P450 3A4 Inhibitors:** The use of strong cytochrome P450 3A4 (CYP3A4) inhibitors (e.g., ritonavir, ketoconazole) with AirDuo RespiClick is not recommended because increased systemic corticosteroid and increased cardiovascular adverse effects may occur.

- **Paradoxical Bronchospasm and Upper Airway Symptoms:** If paradoxical bronchospasm occurs, discontinue AirDuo RespiClick immediately and institute alternative therapy.

- **Hypersensitivity Reactions, Including Anaphylaxis:** Immediate hypersensitivity reactions (e.g., urticaria, angioedema, rash, bronchospasm, hypotension), including anaphylaxis, may occur after administration of AirDuo RespiClick. Discontinue AirDuo RespiClick if such reactions occur.

- **Cardiovascular and Central Nervous System Effects:** Salmeterol, a component of AirDuo RespiClick, can produce clinically significant cardiovascular effects in some patients as measured by pulse rate, blood pressure, and/or symptoms. If such effects occur, AirDuo RespiClick may need to be discontinued. AirDuo RespiClick should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.

- **Reduction in Bone Mineral Density (BMD):** Decreases in BMD have been observed with long-term administration of products containing ICS. Patients with major risk factors for decreased bone mineral content, such as prolonged immobilization, family history of osteoporosis, or chronic use of drugs that can reduce bone mass (e.g., anticonvulsants, oral corticosteroids) should be monitored and treated with established standards of care.

- **Effect on Growth:** ICS, as well as poorly controlled asthma, may cause a reduction in growth velocity, and the long-term effect on final adult height is unknown. Patients should be maintained on the lowest dose of inhaled corticosteroid that effectively controls their asthma. Monitor growth of pediatric patients.

- **Glaucoma and Cataracts:** Long-term use of ICS, including fluticasone propionate, a component of AirDuo RespiClick, may increase the risk for cataracts or glaucoma. Regular eye exams should be considered.

- **Eosinophilic Conditions and Churg-Strauss Syndrome:** Systemic eosinophilic conditions, such as Churg-Strauss syndrome, may occur. Be alert to eosinophilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy.

- **Coexisting Conditions:** Use with caution in patients with convulsive disorders, thyrotoxicosis, diabetes mellitus, ketoacidosis, and in patients who are unusually responsive to sympathomimetic amines.

- **Hypokalemia and Hyperglycemia:** Beta-adrenergic agonist medicines may produce significant hypokalemia in some patients, possibly through intracellular shunting, which has the potential to produce adverse cardiovascular effects.

Please see additional Important Safety Information on the previous pages and Brief Summary of Full Prescribing Information on the following pages.
AirDuo RespiClick® (fluticasone propionate and salmeterol) Inhalation Powder:

ASTHMA CONTROL WITH LESS MEDICINE

Total Daily Dose\(^1\text{-}^3\)

<table>
<thead>
<tr>
<th></th>
<th>AirDuo RespiClick</th>
<th>Authorized Generic</th>
<th>ADVAIR DISKUS®</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Fluticasone propionate + Salmeterol</td>
<td>Fluticasone propionate + Salmeterol</td>
<td>Fluticasone propionate + Salmeterol</td>
</tr>
<tr>
<td>Low</td>
<td>110 mcg + 28 mcg</td>
<td>110 mcg + 28 mcg</td>
<td>200 mcg + 100 mcg</td>
</tr>
<tr>
<td>Medium</td>
<td>226 mcg + 28 mcg</td>
<td>226 mcg + 28 mcg</td>
<td>500 mcg + 100 mcg</td>
</tr>
<tr>
<td>High</td>
<td>464 mcg + 28 mcg</td>
<td>464 mcg + 28 mcg</td>
<td>1000 mcg + 100 mcg</td>
</tr>
</tbody>
</table>

ADVAIR DISKUS® is a registered trademark of the GSK group of companies.

Table is intended to show differences in dosing only and should not be construed to imply safety or efficacy similarities or differences.

IMPORTANT SAFETY INFORMATION for AirDuo RespiClick/Authorized Generic (continued)

- Adverse Reactions: Most common adverse reactions (reported in greater than or equal to 3% of patients) include nasopharyngitis, oral candidiasis, headache, cough and back pain

Please see Important Safety Information on the previous pages and Brief Summary of Full Prescribing Information on the following pages.

References

©2020 Teva Respiratory, LLC. ADR-40314 May 2020
AIRDUO® RESPICLICK® (fluticasone propionate and salmeterol) inhalation powder

ICS/LABA did not show a significantly increased risk of a serious asthma-related event compared to ICS based on the prespecified risk margin (2.7), with an estimated hazard ratio of time to first event of 1.29 (95% CI: 0.73, 2.27).

Salmeterol Multicenter Asthma Research Trial (SMART)
A 28-week, placebo-controlled, U.S. trial that compared the safety of salmeterol with placebo, each added to usual asthma therapy, showed an increase in asthma-related deaths in subjects receiving salmeterol (13/13,176 in subjects treated with salmeterol versus 3/13,179 in subjects treated with placebo; relative risk: 4.37 (95% CI: 1.25, 15.34)). Use of background ICS was not required in SMART. The increased risk of asthma-related death is considered a class effect of LABA monotherapy.

5.2 Deterioration of Disease and Acute Episodes
AIRDUO RESPICLICK should not be initiated in patients during rapidly deteriorating or potentially life-threatening episodes of asthma. AIRDUO RESPICLICK has not been studied in subjects with acutely deteriorating asthma. The initiation of AIRDUO RESPICLICK in this setting is not appropriate.

Serious acute respiratory events, including fatalities, have been reported when salmeterol, a component of AIRDUO RESPICLICK, has been initiated in patients with significantly worsening or acutely deteriorating asthma. In most cases, these have occurred in patients with severe asthma (e.g., patients with a history of corticosteroid dependence, low pulmonary function, intubation, mechanical ventilation, frequent hospitalizations, previous life-threatening asthma exacerbations) and in some patients with acutely deteriorating asthma, patients with significantly increasing symptoms; increasing need for inhaled, short-acting beta-agonists; decreasing response to usual medications; increasing need for systemic corticosteroids; recent exacerbations (within 1–24 hours), requiring hospitalization. These adverse events have occurred in a few patients with less severe asthma as well. It was not possible from these reports to determine whether salmeterol contributed to these events.

Increasing use of inhaled, short-acting beta-agonists is a marker of deteriorating asthma. In this situation, the patient requires immediate reevaluation with reassessment of the treatment regimen, giving special consideration to the possible need for replacing the current strength of AIRDUO RESPICLICK with a higher strength, adding additional inhaled corticosteroid, or initiating systemic corticosteroids. Patients should not use more than 1 inhalation twice daily of AIRDUO RESPICLICK.

AIRDUO RESPICLICK should not be used for the relief of acute asthma symptoms, i.e., as rescue therapy for the treatment of acute episodes of bronchospasm. An inhaled, short-acting beta-agonist, not AIRDUO RESPICLICK, should be used to relieve acute symptoms such as shortness of breath. When prescribing AIRDUO RESPICLICK, the healthcare provider should also prescribe an inhaled, short-acting beta-agonist (e.g., albuterol) for treatment of acute symptoms, despite regular twice-daily use of AIRDUO RESPICLICK.

When beginning treatment with AIRDUO RESPICLICK, patients who have been taking oral or inhaled, short-acting beta-agonists on a regular basis (e.g., 4 times a day) should be instructed to discontinue the regular use of these drugs.

5.3 Excessive Use of AIRDUO RESPICLICK and Use with Other Long-Acting Beta-2-Agonists
AIRDUO RESPICLICK should not be used more often than recommended, at higher doses than recommended, or in conjunction with other medicines containing LABA, as an overdose may result. Clinically significant cardiovascular effects and fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs. Patients using AIRDUO RESPICLICK should not use another medicine containing a LABA (e.g., salmeterol, formoterol fumarate, arformoterol tartrate, indacaterol) for any reason.

5.4 Local Effects of Inhaled Corticosteroids
In clinical trials, the development of localized infections of the mouth and pharynx with Candida albicans has occurred in subjects treated with AIRDUO RESPICLICK. When such an infection develops, it should be treated with appropriate local therapy (i.e., oral antifungal therapy while treatment with AIRDUO RESPICLICK continues, but at times when therapy with AIRDUO RESPICLICK may need to be interrupted. Advice the patient to rinse his/her mouth with water without swallowing following inhalation to help reduce the risk of oropharyngeal candidiasis.

5.5 Immunosuppression
Persons who are using drugs that suppress the immune system are more susceptible to infections than healthy individuals. Chickenpox and measles, for example, can have more serious or even fatal courses in susceptible adolescents or adults using corticosteroids. In such patients who have not had these diseases or who have not been properly immunized, particular care should be taken to avoid exposure. How the dose, route and duration of corticosteroid administration affect the risk of developing a disseminated infection is not known. The contribution of the underlying disease and/or prior corticosteroid treatment to the risk is also not known. If a patient is exposed to varicella, prophylaxis with varicella-zoster immune globulin (VZIG) or pooled intravenous immunoglobulin (IVIG) may be indicated. If a patient is exposed to measles, prophylaxis with pooled intramuscular immunoglobulin (IG) may be indicated. (See respective package inserts for complete VZIG and IG prescribing information.) If chickenpox develops, treatment with antiviral agents may be considered.

Inhaled corticosteroids should be used with caution, if at all, in patients with active or quiescent tuberculosis infections of the respiratory tract; systemic fungal, bacterial, viral, or parasitic infections; or ocular herpes simplex.

5.6 Transferring Patients from Systemic Corticosteroid Therapy
Guidance for patients who are transferred from systemically active corticosteroids to inhaled corticosteroids because deaths due to adrenal insufficiency have occurred in patients with asthma during and after transfer from systemic corticosteroids to less systemically available inhaled corticosteroids. After withdrawal from systemic corticosteroids, a number of months are required for recovery of hypothalamic-pituitary-adrenal (HPA) function.
Patients who have been previously maintained on 20 mg or more of prednisone (or its equivalent) may be more susceptible, particularly when their systemic corticosteroids have been almost completely withdrawn. During this period of HPA suppression, patients may exhibit signs and symptoms of adrenal insufficiency when exposed to trauma, surgery, or infection (particularly gastrointestinal), or other conditions associated with severe electrolyte loss. Although AIRDUO RESPICLICK may improve control of asthma symptoms during these episodes, in recommended doses it supplies less than normal physiological amounts of corticosteroid systemically and does NOT provide the mineralocorticoid activity that is necessary for coping with these emergencies. During periods of stress or a severe asthmatic attack, patients who have been withdrawn from systemic corticosteroids should be instructed to resume oral corticosteroids (in large doses) immediately and to contact their physician for further instruction. These patients should also be instructed to carry a medical identification warning card indicating that they may need supplementary systemic corticosteroids during periods of stress or a severe asthma attack.

Patients requiring systemic corticosteroids should be weaned slowly from systemic corticosteroids to AIRDUO RESPICLICK. Lung function (measured forced expiratory volume in 1 second [FEV], or morning peak expiratory flow [AM PEF]), beta-agonist use, and asthma symptoms should be carefully monitored during withdrawal of systemic corticosteroids, some patients may experience symptoms of adrenal insufficiency (e.g., fatigue, malaise, nausea, and vomiting) during adrenal suppression (including adrenal crisis) may appear in a small number of patients who are sensitive to these effects. If such effects occur, AIRDUO RESPICLICK should be discontinued. Close monitoring of patients is warranted in patients with a change in vision or with a history of increased intraocular pressure, glaucoma, and/or cataracts. The occurrence of cataracts with long-term treatment with fluticasone propionate and salmeterol has been reported in patients receiving AIRDUO RESPICLICK. In a 3-year survival trial of COPD in the 3-year survival trial. Ophthalmic examinations were conducted at baseline and at 48, 108, and 158 weeks. Conclusions about cataracts cannot be drawn from this trial because the high incidence of cataracts at baseline (61% to 71%) resulted in inadequate numbers of subjects with COPD. To evaluate the development of cataracts or glaucoma was 2% with other Fluticasone Propionate and Salmeterol Inhalation Powder 500 mcg/50 mcg, fluticasone propionate 500 mcg, salmeterol 50 mcg, or placebo on development of cataracts or glaucoma was 2% with other Fluticasone Propionate and Salmeterol Inhalation Powder 500 mcg/50 mcg who were eligible and available for evaluation of cataracts at the end of the trial (n = 55). The incidence of newly diagnosed cataracts was 2% with other Fluticasone Propionate and Salmeterol Inhalation Powder 500 mcg/50 mcg, 5% with fluticasone propionate, 0% with salmeterol, and 2% with placebo. AIRDUO RESPICLICK, may present with systemic eosinophilic conditions. Some of these patients have clinical features of vasculitis consistent with Churg-Strauss syndrome, a condition that is often treated with systemic corticosteroid therapy. These events usually, but not always, have been associated with the reduction and/or withdrawal of oral corticosteroid therapy following the introduction of fluticasone propionate. Cases of serious eosinophilic conditions have also been reported with other inhaled corticosteroids in this clinical setting. Physicians should be alert to eosinophilia, vasculitis, rash, worsening pulmonary symptoms, cardiac complications, and/or neurophysiologic symptoms in their patients. A causal relationship between fluticasone propionate and these underlying conditions has not been established.

5.5 Cardiovascular and Central Nervous System Effects

Systolic blood pressure, glaucoma, and/or cataracts. Effects of treatment with other Fluticasone Propionate and Salmeterol Inhalation Powder 500 mcg/50 mcg, fluticasone propionate 500 mcg, salmeterol 50 mcg, or placebo on development of cataracts or glaucoma was 2% with other Fluticasone Propionate and Salmeterol Inhalation Powder 500 mcg/50 mcg who were eligible and available for evaluation of cataracts at the end of the trial (n = 55). The incidence of newly diagnosed cataracts was 2% with other Fluticasone Propionate and Salmeterol Inhalation Powder 500 mcg/50 mcg, 5% with fluticasone propionate, 0% with salmeterol, and 2% with placebo. AIRDUO RESPICLICK, may present with systemic eosinophilic conditions. Some of these patients have clinical features of vasculitis consistent with Churg-Strauss syndrome, a condition that is often treated with systemic corticosteroid therapy. These events usually, but not always, have been associated with the reduction and/or withdrawal of oral corticosteroid therapy following the introduction of fluticasone propionate. Cases of serious eosinophilic conditions have also been reported with other inhaled corticosteroids in this clinical setting. Physicians should be alert to eosinophilia, vasculitis, rash, worsening pulmonary symptoms, cardiac complications, and/or neurophysiologic symptoms in their patients. A causal relationship between fluticasone propionate and these underlying conditions has not been established.

5.6 Drug Interactions with Strong Cytochrome P450 3A4 Inhibitors

Theophylline ( Theo-Dur® CYP3A4 (CYP3A4 inhibitors) (e.g., ritonavir, atazanavir, clarithromycin, indinavir, itraconazole, nefazodone, neflinavin, saquinavir, ketocenazole, telithromycin) with AIRDUO RESPICLICK is not recommended because increased systemic corticosteroid and increased cardiovascular adverse effects may occur [See Drug Interactions (7.1)].

5.7 Paradoxical Bronchospasm and Upper Airway Symptoms

As with other beta-agonist medicines, AIRDUO RESPICLICK can produce paradoxical bronchospasm, which may be life-threatening. If paradoxical bronchospasm occurs following dosing with inhaled fluticasone propionate/salmeterol medicines, it should be treated by the provider. In patients receiving AIRDUO RESPICLICK should be discontinued immediately; and alternative therapy should be instituted. Upper airway symptoms of laryngeal spasm, irritation, or swelling, such as stridor and choking, have been reported in patients receiving inhaled fluticasone propionate/salmeterol medicines. Monitor the growth of pediatric patients receiving AIRDUO RESPICLICK routinely (e.g., via stadiometry). To minimize the systemic effects of orally inhaled corticosteroids, including AIRDUO RESPICLICK, titrate each patient's dosage to the lowest dosage that effectively controls his/her symptoms [see Use in Specific Populations (8.4)].

5.8 Paradoxical Bronchospasm and Upper Airway Symptoms

5.9 Paradoxical Bronchospasm and Upper Airway Symptoms

5.10 Hypersensitivity Reactions, Including Anaphylaxis

Immediate hypersensitivity reactions (e.g., urticaria, angioedema, rash, bronchospasm, hypotension), including anaphylaxis, may occur after administration of AIRDUO RESPICLICK. There have been reports of anaphylactic reactions in patients with severe milk protein allergy after inhalation of dry powder products containing lactose; therefore, patients with severe milk protein allergy should not use AIRDUO RESPICLICK [see Contraindications (4)].

5.10 Hypersensitivity Reactions, Including Anaphylaxis

5.11 Cardiovascular and Central Nervous System Effects

Excessive beta-adrenergic stimulation has been associated with seizures, angina, hypertension or hypotension, tachycardia with rates up to 200 beats/min, arrhythmias, nervousness, headache, tremor, palpitation, nausea, dizziness, fatigue, malaise, and insomnia [see Overdosage (10)]. Therefore, AIRDUO RESPICLICK, like all products containing sympathomimetic amines, should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.
AIRDUO® RESPICLICK® (fluticasone propionate and salmeterol) inhalation powder

6.1 Clinical Trials Experience in Asthma

Because clinical trials are conducted under widely varying conditions, adverse reaction rates in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. In two placebo-controlled, 12-week, clinical studies (Trials 1 and 2), a total of 1,364 adolescent and adult patients with persistent symptomatic asthma despite ICS or ICS/LABA therapy were treated twice daily with either placebo; fluticasone propionate 113 mcg or 232 mcg or ARMONAIR RESPICLICK hereafter referred to as fluticasone propionate MDPI; or AIRDUO RESPICLICK 55 mcg/14 mcg, 113 mcg/14 mcg, or 232 mcg/14 mcg. Sixty percent of patients were female and 80% of patients were white. The average duration of exposure was 82 to 84 days in the fluticasone propionate MDPI and AIRDUO RESPICLICK treatment groups compared with 75 days in the placebo group. Table 2 displays the incidence of most common adverse reactions in pooled Trials 1 and 2.

Table 2: Adverse Reactions with ≥3% Incidence with AIRDUO RESPICLICK and More Common than with Placebo in Subjects with Asthma (Trials 1 and 2)

| Adverse Reaction | Fluticasone Propionate MDPI | Fluticasone Propionate MDPI | AIRDUO RESPICLICK 55 mcg/14 mcg | AIRDUO RESPICLICK 113 mcg/14 mcg | Placebo
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(n=129)</td>
<td>(n=239)</td>
<td>(n=244)</td>
<td>(n=146)</td>
<td>(n=128)</td>
<td>(n=129)</td>
</tr>
<tr>
<td>Nausea</td>
<td>1.6</td>
<td>0.9</td>
<td>2.3</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Headache</td>
<td>1.6</td>
<td>2.0</td>
<td>2.5</td>
<td>3.1</td>
<td>4.3</td>
</tr>
<tr>
<td>Cough</td>
<td>1.6</td>
<td>1.8</td>
<td>3.4</td>
<td>2.3</td>
<td>2.6</td>
</tr>
</tbody>
</table>

* Oral candidiasis includes oropharyngeal candidiasis, oral fungal infection, and oropharyngitis fungal

Other adverse reactions not previously listed (and occurring in <3% of patients and in three or more patients on AIRDUO RESPICLICK) that were reported more frequently by patients with asthma treated with AIRDUO RESPICLICK compared with patients treated with placebo include the following:

Respiratory, Thoracic, and Mediastinal Disorders: Chest congestion; chest tightness, bronchospasm; tracheitis; wheezing; reports of upper respiratory symptoms of uncertain size, it is not always possible to reliably estimate their frequency or establish a cause-and-effect relationship to fluticasone propionate and/or salmeterol or a combination of these factors.

Musculoskeletal, Connective Tissue, and Bone Disorders: Arthralgia, cramps, myositis, hyperactivity and irritability, have been reported very rarely and primarily in children.

Immune System Disorders: Immediate and delayed hypersensitivity reaction (including anaphylaxis). Very rare anaphylactic reaction in patients with severe milk protein allergy.

7 DRUG INTERACTIONS

AIRDUO RESPICLICK has been used concomitantly with other drugs, including short-acting beta-agonists, and intransal corticosteroids, commonly used in patients with asthma via MDPI 55 mcg, 113 mcg. No formal drug interaction trials have been performed with AIRDUO RESPICLICK.

7.1 Inhibitors of Cytochrome P450 3A4

Fluticasone propionate and salmeterol, the individual components of AIRDUO RESPICLICK, are substrates of CYP3A4. The use of strong CYP3A4 inhibitors (e.g., ritonavir, atazanavir, clarithromycin, indinavir, itraconazole, nefazodone, nelfinavir, saquinavir, and/or ritonavir) with AIRDUO RESPICLICK is not recommended because they increased systemic corticosteroid and increased cardiovascular adverse effects may occur.

Ritonavir—Fluticasone Propionate: A drug interaction trial with fluticasone propionate aqueous nasal spray in healthy subjects has shown that ritonavir (a strong CYP3A4 inhibitor) can significantly increase plasma fluticasone propionate exposure, resulting in significantly reduced serum cortisol concentrations. During postmarketing use, there have been reports of clinically significant drug interactions in patients receiving fluticasone propionate and ritonavir, resulting in systemic corticosteroid effects such as cushingoid syndrome and adrenal suppression.

Ketozolace: Fluticasone Propionate: Coadministration of orally inhaled fluticasone propionate (1,000 mcg) and ketoconazole (200 mg once daily) resulted in a 2-fold increase in plasma fluticasone propionate exposure and a 45% decrease in plasma cortisol area under the curve (AUC) but had no effect on urinary excretion of cortisol.

Salmeterol: In a drug interaction trial in 20 healthy subjects, coadministration of inhaled salmeterol (50 mcg twice daily) and oral ketoconazole (400 mg once daily) for 7 days resulted in greater systemic exposure to salmeterol (AUC increased 1.6-fold and Cmax increased 1.4-fold). Three (3) subjects were withdrawn due to beta-agonist side effects (2 with prolonged QTc and 1 with palpitations and sinus tachycardia).

There was no statistically significant effect on the mean QTc, coadministration of salmeterol and ketoconazole was associated with more frequent increases in QTc duration compared with salmeterol and placebo administration.

7.2 Monoamine Oxidase Inhibitors and Tricyclic Antidepressants

AIRDUO RESPICLICK should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors or tricyclic antidepressants, or within 2 weeks of discontinuation of such agents, because the action of salmeterol, a component of AIRDUO RESPICLICK, on the vascular system may be potentiated by these agents.

7.3 Beta-Adrenergic Receptor Blocking Agents

Beta-blockers not only block the pulmonary effect of beta-agonists, such as salmeterol, a component of AIRDUO RESPICLICK, but may also produce severe bronchospasm in patients with asthma. Therefore, patients with asthma should not normally be treated with beta-blockers. However, under certain circumstances, there may be no acceptable alternatives to the use of beta-adrenergic blocking agents for these patients.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no randomized clinical studies of AIRDUO RESPICLICK or individual components, fluticasone propionate and salmeterol, in pregnancy in women. There are no clinical considerations with the use of AIRDUO RESPICLICK in pregnant women. Experience with oral corticosteroids is limited. Experience with oral corticosteroids suggests that rodents are more prone to teratogenic effects from corticosteroids than humans. Oral administration of salmeterol to pregnant rabbits caused teratogenic characteristic of beta-adrenergic receptor stimulation at maternal doses approximately 700 times the MRHDID when salmeterol was administered by the oral route to achieve high systemic exposures. No such effects occurred at an oral salmeterol dose approximately 420 times the MRHDID . These adverse effects generally occurred at large multiples of the MRHDID when salmeterol was administered by the oral route to achieve high systemic exposures. No such effects occurred at an oral salmeterol dose approximately 420 times the MRHDID .
In two embryo/fetal development studies, pregnant rats received salmeterol by oral administration at doses ranging from 100 to 10,000 mcg/kg/day during the period of organogenesis. Salmeterol produced no maternal toxicity or embryofetal effects at doses up to 3500 times the MRHDID (on a mcg/m² basis at maternal oral doses up to 10,000 mcg/kg/day).

In post-natal development study in pregnant rats dosed by the oral route from late gestation through delivery and lactation, salmeterol at a dose 3500 times the MRHDID (on mcg/m² basis with a maternal oral dose of 10,000 mcg/kg/day) was not toxic and decreased the fertility of survivors. Salmeterol xinafoate crossed the placenta following oral administration to mice and rats.

8.2 Lactation

There are no available data on the presence of fluticasone propionate or salmeterol in human milk, the effects on the breastfed child, or the effects on milk production. Other corticosteroids have been detected in human milk. However, fluticasone propionate and salmeterol concentrations in plasma after inhaled therapeutic doses are low and therefore concentrations in human breast milk are likely to be correspondingly low. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for AIRDUO RESPICLICK and any potential adverse effects on the breastfed child from AIRDUO RESPICLICK or from the underlying maternal condition.

Data

Animal Data

Subcutaneous administration of fluticasone propionate at a dose in lactating rats approximately 0.2 times the MRHDID for adults (on a mcg/m² basis) resulted in measurable levels in milk. Oral administration of salmeterol at a dose approximately 1470 times the MRHDID (on a mcg/m² basis at a maternal oral dose of 10,000 mcg/kg/day). No developmental toxicity was observed at combination doses of fluticasone propionate at a dose up to approximately 0.57 mcg/kg/day) and salmeterol at a dose of 30 mcg/kg/day. Cleft palate and fetal skeletal variations were observed in mouse fetuses with a maternal subcutaneous dose of 0.08 mcg/kg/day). The mouse NOAEL was observed at approximately 0.16 times the MRHDID (on a mcg/m² basis with a maternal subcutaneous dose of 45 mcg/kg/day). The mouse NOAEL was observed at approximately 0.5 times the MRHDID (on a mcg/m² basis with a maternal subcutaneous dose of 25.7 mcg/kg/day); however, there was no evidence of teratogenicity. The NOAEL was observed at a dose approximately 0.1 times the MRHDID (on a mcg/m² basis with a maternal inhalation dose of 5.5 mcg/kg/day).

In an embryo/fetal development study with pregnant rats that were dosed by the inhalation route throughout the period of organogenesis, fluticasone propionate produced decreased fetal body weights and skeletal variations, in the presence of maternal toxicity, at a dose approximately 0.5 times the MRHDID (on a mcg/m² basis with a maternal inhalation dose of 25.7 mcg/kg/day); however, there was no evidence of teratogenicity. The NOAEL was observed at a dose approximately 0.1 times the MRHDID (on a mcg/m² basis with a maternal subcutaneous dose of 15 mcg/kg/day). The rat NOAEL was observed at approximately 0.8 times the MRHDID (on a mcg/m² basis with a maternal subcutaneous dose up to 50 mcg/kg/day). In an embryo/fetal development study with pregnant mice that received the combination of subcutaneous administration of fluticasone propionate and oral administration of salmeterol at doses ranging from 100/1440, 40/0, 40/1400, or 150/10,000 mcg/kg/day) and a dose of salmeterol at approximately 3500 times the MRHDID (on a mcg/m² basis at a maternal oral dose of 10,000 mcg/kg/day) and a dose of salmeterol at approximately 3500 times the MRHDID (on a mcg/m² basis at a maternal oral dose of 10,000 mcg/kg/day). The rat NOAEL was observed when combining fluticasone propionate at a dose approximately 2 times the MRHDID (on a mcg/m² basis at a maternal subcutaneous dose of 100 mcg/kg/day) and a dose of salmeterol at approximately 3500 times the MRHDID (on a mcg/m² basis at a maternal oral dose of 10,000 mcg/kg/day). The rat NOAEL was observed when combining fluticasone propionate at a dose approximately 2 times the MRHDID (on a mcg/m² basis at a maternal subcutaneous dose of 100 mcg/kg/day) and a dose of salmeterol at approximately 3500 times the MRHDID (on a mcg/m² basis at a maternal oral dose of 10,000 mcg/kg/day). The rat NOAEL was observed when combining fluticasone propionate at a dose approximately 1.4 times the MRHDID (on a mcg/m² basis at a maternal subcutaneous dose of 151 mcg/kg/day) and salmeterol at a dose approximately 1470 times the MRHDID (on a mcg/m² basis at a maternal oral dose of 10,000 mcg/kg/day). No developmental toxicity was observed at combination doses of fluticasone propionate at a dose up to approximately 0.57 mcg/kg/day) and salmeterol at the time the MRHDID (on a mcg/m² basis at a maternal subcutaneous dose of 40 mcg/kg) and doses of salmeterol up to approximately 420 times the MRHDID (on a mcg/m² basis at a maternal oral dose of 1470 mcg/kg).

Fluticasone Propionate: In embryo/fetal development studies with pregnant rats and mice dosed by the subcutaneous route throughout the period of organogenesis, fluticasone propionate was teratogenic in both species. Omphalocele, decreased body weight, and skeletal variations were observed in rat fetuses, in the presence of maternal toxicity, at a dose approximately 2 times the MRHDID (on a mcg/m² basis with a maternal subcutaneous dose of 30 mcg/kg/day). Cleft palate and fetal skeletal variations were observed in mouse fetuses at a dose approximately 0.5 times the MRHDID (on a mcg/m² basis at a maternal subcutaneous dose of 45 mcg/kg/day). The mouse NOAEL was observed with a dose approximately 0.16 times the MRHDID (on a mcg/m² basis with a maternal subcutaneous dose of 45 mcg/kg/day). The mouse NOAEL was observed at approximately 0.8 times the MRHDID (on a mcg/m² basis at a maternal subcutaneous dose of 15 mcg/kg/day). The rat NOAEL was observed at approximately 0.5 times the MRHDID (on a mcg/m² basis with a maternal inhalation dose of 5.5 mcg/kg/day).

In an embryo/fetal development study with pregnant rats that were dosed by the subcutaneous route throughout organogenesis, fluticasone propionate produced decreased fetal body weights and skeletal variations, in the presence of maternal toxicity, at a dose approximately 0.2 times the MRHDID and higher (on a mcg/m² basis with a maternal subcutaneous dose of 0.57 mcg/kg/day). Teratogenicity was evident based upon a finding of cleft palate for 1 fetus at a dose approximately 0.2 times the MRHDID (on a mcg/m² basis with maternal subcutaneous doses up to 50 mcg/kg/day). The rat NOAEL was observed at approximately 0.08 times the MRHDID (on a mcg/m² basis at a maternal oral dose of 10,000 mcg/kg/day). Cleft palate and fetal skeletal variations were observed in mouse fetuses with a maternal subcutaneous dose of 0.08 mcg/kg/day). The mouse NOAEL was observed with a dose approximately 0.16 times the MRHDID (on a mcg/m² basis with a maternal subcutaneous dose of 45 mcg/kg/day). The mouse NOAEL was observed at approximately 0.5 times the MRHDID (on a mcg/m² basis with a maternal subcutaneous dose of 15 mcg/kg/day). The rat NOAEL was observed at approximately 0.8 times the MRHDID (on a mcg/m² basis at a maternal subcutaneous dose up to 50 mcg/kg/day).

In an embryo/fetal development study with pregnant rats that were dosed by the subcutaneous route throughout organogenesis, fluticasone propionate produced decreased fetal body weights, in the presence of maternal toxicity, at a dose approximately 0.02 times the MRHDID and higher (on a mcg/m² basis with a maternal subcutaneous dose of 0.57 mcg/kg/day). Teratogenicity was evident based upon a finding of cleft palate and/or lip and jaw flexures, and delayed ossification of the maxillary bones at a dose of 0.57 mcg/kg/day). The NOAEL was observed in rabbit fetuses with a dose approximately 0.004 times the MRHDID (on a mcg/m² basis at a maternal subcutaneous dose of 0.08 mcg/kg/day).

In a pre- and post-natal development study in pregnant rats dosed by the subcutaneous route from late gestation through delivery and lactation (Gestation Day 17 to Postpartum Day 22), fluticasone propionate was not associated with decreases in pup body weight, and had no effects on developmental landmarks, learning, memory, reflexes, or fertility at doses up to approximate equivalence to the MRHDID (on a mcg/m² basis at maternal condition).

In a pre- and post-natal development study in pregnant rats dosed by the subcutaneous route from late gestation through delivery and lactation (Gestation Day 17 to Postpartum Day 22), fluticasone propionate was not associated with decreases in pup body weight, and had no effects on developmental landmarks, learning, memory, reflexes, or fertility at doses up to approximate equivalence to the MRHDID (on a mcg/m² basis at maternal condition).

In a pre- and post-natal development study in pregnant rats dosed by the subcutaneous route from late gestation through delivery and lactation (Gestation Day 17 to Postpartum Day 22), fluticasone propionate was not associated with decreases in pup body weight, and had no effects on developmental landmarks, learning, memory, reflexes, or fertility at doses up to approximate equivalence to the MRHDID (on a mcg/m² basis at maternal condition).

8.4 Pediatric Use

In patients with hepatic impairment. However, since both fluticasone propionate and salmeterol are predominantly cleared by hepatic metabolism, impairment of liver function may lead to accumulation of fluticasone propionate and salmeterol in plasma. Therefore, patients with hepatic impairment should be closely monitored.

10. OVERDOSAGE

AIRDUO RESPICLICK contains both fluticasone propionate and salmeterol; therefore, the risks associated with overdose for the individual components described below apply to AIRDUO RESPICLICK. Treatment of overdose consists of discontinuation of AIRDUO RESPICLICK together with institution of appropriate symptomatic and/or supportive therapy. The judicious use of a cardiac specific beta-receptor blocker may be considered, bearing in mind that such medication can produce bronchospasm. Cardiac monitoring is recommended in cases of overdose.

Fluticasone propionate

Chronic overdosage of fluticasone propionate may result in signs/symptoms of systemic corticosteroid toxicity (see Warnings and Precautions (5.7)). Inhalation by healthy volunteers of a single dose of 4,000 mcg of fluticasone propionate inhalation powder or single doses of 1,760 or 3,520 mcg of fluticasone propionate CFC inhalation powder was well tolerated. Fluticasone propionate given by inhalation aerosol in single doses of 1,320 mcg twice daily for 7 to 15 days to healthy human volunteers was also well tolerated. Repeat oral doses up to 80 mg daily for 10 days in healthy volunteers and repeat oral doses up to 20 mg daily for 42 days in subjects were well tolerated. Adverse reactions were of mild or moderate severity, and incidences were similar in active and placebo treatment groups.
AIRDUO® RESPICLICK® (fluticasone propionate and salmeterol) inhalation powder

Salmeterol

The expected signs and symptoms with overdosage of salmeterol are those of excessive beta-adrenergic stimulation and/or occurrence or exaggeration of any of the signs and symptoms of beta-adrenergic stimulation (e.g., seizures, angina, hypertension or hypotension, tachycardia with rates up to 200 beats/min, arrhythmias, nervousness, headache, tremor, muscle cramps, dry mouth, palpitation, nausea, dizziness, fatigue, malaise, insomnia, hyperglycemia, hypokalemia, metabolic acidosis). Overdosage with salmeterol can lead to clinically significant prolongation of the QTc interval, which can produce ventricular arrhythmias.

As with all inhaled sympathomimetic medicines, cardiac arrest and even death may be associated with an overdose of salmeterol.

Distributed by: Teva Pharmaceuticals USA, Inc.
Parsippany, NJ 07054

©2020 Teva Respiratory, LLC
All rights reserved.


This brief summary is based on the AIRDUO® RESPICLICK® full prescribing information AIPDI-005.

teva

ADR-40311 April 2020
Your Voice Matters

To keep their pharmacies viable during this challenging time, pharmacists should take action—on both the federal and state levels. By Jennifer Barrett

Many of the challenges that independent pharmacies have faced for years have become even more apparent during the coronavirus disease 2019 (COVID-19) pandemic, highlighting the need for action in several legislative areas.

During ThoughtSpot Live 2020—Good Neighbor Pharmacy’s annual independent community pharmacy conference and trade show, held virtually this year—Bob Mauch, PharmD, RPh, executive vice president and group president of AmerisourceBergen, and Beth Mitchell, senior director of Government Affairs for AmerisourceBergen, talked with Drug Topics® about the importance of advocacy during this time and the legislative priorities that independent pharmacists should keep an eye on for the future.

Since March, AmerisourceBergen and Good Neighbor Pharmacy (GNP) have met with more than 300 federal and state legislators and staff through video and phone calls, continuing to make an impact on pharmacy-policy priorities amid COVID-19.

Expanded Immunization Authority

The US Department of Health & Human Services (HHS) recently authorized pharmacists to order/administer COVID-19 vaccinations (once available) to persons aged 3 years and older. In August, HHS also authorized state-licensed pharmacists to order/administer all CDC-recommended and FDA-approved vaccines for persons aged 3 to 18 years to increase vaccine access for children during the pandemic. HHS was able to authorize both measures under the Public Readiness and Emergency Preparedness Act to ensure increased vaccine access in the US. The authorizations preempt state and local laws that prohibit or effectively prohibit those who satisfy requirements from ordering or administering vaccines.

“This news is a huge win, but we’re still pushing for more,” Mauch told Drug Topics®. “These actions are certainly good steps in the right direction and they show that the government is thinking about the important role that pharmacists and community pharmacy can play in the immunization process, but it should be much more broad, frankly, to include empowering and reimbursing pharmacists for providing immunizations and other services to patients during and beyond COVID-19.”

In addition, several questions remain about how pharmacists will be reimbursed by payers for this service. Mauch noted that GNP and AmerisourceBergen will continue to work with manufacturers and pharmacy partners in several pharmacy trade associations and the American Disease Prevention Coalition to monitor these concerns.

Mitchell noted that pharmacists should continue to encourage their own state legislatures in support of legisla-

With the need for millions of immunizations to be given rapidly once a COVID-19 vaccine becomes available, the role of pharmacists is going to become even more critical.”

BOB MAUCH, PHARMD, RPH, EXECUTIVE VICE PRESIDENT AND GROUP PRESIDENT OF AMERISOURCEBERGEN

improvements are still needed. “We’ve got to do more,” she said. “We have to think about how we need as many access points for all vaccinations as possible. Pharmacists are so well positioned to do this.”

On the state level, more legislation is being passed to provide pharmacists the authority to administer FDA-authorized COVID-19 vaccines to eligible individuals, once a vaccine becomes available. Minnesota became the first state to pass this kind of legislation, with Minnesota Governor Tim Walz signing the comprehensive bill into law on May 27. Several states, such as New York and New Hampshire, are now following suit.

Mitchell noted that pharmacists should continue to encourage their own state legislatures in support of legisla-

To keep their pharmacies viable during this challenging time, pharmacists should take action—on both the federal and state levels.
“I think our customers and pharmacists have the most impactful voice on legislative issues they care about, especially since they are providers and leaders in their communities.”

BETH MITCHELL, SENIOR DIRECTOR OF GOVERNMENT AFFAIRS FOR AMERISOURCEBERGEN

As we continue to manage the current pandemic and in the long term for chronic disease management, pharmacists are going to become even more critical. According to Mauch, provider status on a broad level that allows pharmacists to bill for these types of clinical services is necessary to their customers and their patients, they also have to have an economically viable business,” Mauch said. “We’re continuing to educate our elected officials on the importance of this issue,” Mitchell said. “Some elected officials have concerns that if DIR fees were to be passed on at the point of sale, Medicare beneficiaries would see changes in premiums.”

However, patients already struggle with the consequences of DIR fees and a lack of transparency in the industry. Mitchell cited a recent CoverMyMeds survey that found that 75% of patients received a prescription that cost more than they expected, indicating that these punitive fees are harming both pharmacies and patients.

“We’re really trying to help pharmacists and patients see some relief on this issue,” Mitchell said. “I think it’s so important now because we are living in the current pandemic, and we want to make sure pharmacists don’t have additional pressures facing their business and their patients.”

**Granting Pharmacists Provider Status**

According to Mauch, national leaders must recognize pharmacists as providers under Medicare Part B, not only to assist the response to COVID-19 but also to support public health initiatives going forward.

Pharmacists’ ability to care for patients, either through administering immunizations or flu tests, varies by state, service, and payer type. Pharmacists are not currently recognized as providers in Medicare, and it is the hope that if Congress establishes pharmacists as providers in Medicare Part B.

“The legislation we’re working on now would require Medicare to recognize pharmacists as providers in Part B, and pharmacists would be reimbursed for services they provide during the pandemic,” such as a COVID-19 and flu tests and COVID-19 and flu vaccinations, Mitchell said.

**Direct and Indirect Remuneration Fee Reform**

Direct and indirect remuneration (DIR) fees are one of the biggest challenges facing community pharmacy right now, Mauch said. Currently, there is legislation in Congress that would eliminate DIR fees.

“While the pharmacist’s primary focus is on providing clinical services to their customers and their patients, they also have to have an economically viable business,” Mauch said. “We’re continuing to educate our elected officials on the importance of this issue,” Mitchell said. “Some elected officials have concerns that if DIR fees were to be passed on at the point of sale, Medicare beneficiaries would see changes in premiums.”

However, patients already struggle with the consequences of DIR fees and a lack of transparency in the industry. Mitchell cited a recent CoverMyMeds survey that found that 75% of patients received a prescription that cost more than they expected, indicating that these punitive fees are harming both pharmacies and patients.

“We’re really trying to help pharmacists and patients see some relief on this issue,” Mitchell said. “I think it’s so important now because we are living in the current pandemic, and we want to make sure pharmacists don’t have additional pressures facing their business and their patients.”

**Other Areas to Watch**

Pharmacists should also watch for a future COVID-19 stimulus or response legislation in Congress, Mitchell said. Congress has passed several major pieces of legislation over the past several months that have been signed into law. “Many of those bills have been beneficial for small businesses, including independent pharmacies,” said Mitchell, including programs such as the Paycheck Protection Program and other small-business loans.

To move advocacy efforts forward, AmerisourceBergen and GNP continue to partner with a number of industry coalitions, state pharmacy associations, and boards of pharmacy to advance key issues in the increasingly contested legislative environment. Pharmacists can also get involved at both the state and federal levels to help propel advocacy on issues that are important to them.

“I think the best organization we partner with to promote advocacy are our customers and pharmacists who really take the time to get engaged,” Mitchell said. “I think our customers and pharmacists have the most impactful voice on legislative issues they care about, especially since they are providers and leaders in their communities. Elected officials want to hear from their constituents, especially those who are providing care to their constituents.”

This article was written in partnership with AmerisourceBergen and Good Neighbor Pharmacy.
Never miss a thing.

Pipeline snapshots.
Industry news.
Conference reports.

Sign up for the Drug Topics® eNewsletter.

Take us anywhere.

drugtopics.com/enews
The coronavirus disease 2019 (COVID-19) pandemic has undeniably placed a significant burden on patients with cancer receiving chemotherapy and other medications and services. However, oncology pharmacists quickly adapted, learning new ways to communicate with patients, schedule visits and treatments, and reevaluate their medications regimens.

For example, patient visits at Allegheny Health Network’s Cancer Institute in Pittsburgh, Pennsylvania, which operates more than 20 oncology infusion clinics, have been reduced to help avoid exposure to COVID-19. Before the pandemic, patients visited the clinic 2 days before each scheduled chemotherapy appointment for laboratory work and consultations. Now those visits are held on the same day as the chemotherapy treatment, Danielle Roman, PharmD, BOCPP, manager of clinical pharmacy services for Allegheny Health Network Cancer Institute, told the American Journal of Health-System Pharmacy.1

“For some of our patients who have been on treatment for many cycles and have had very stable labs, we felt more comfortable...minimizing lab draws...and just having them done around the time of each treatment,” Roman said.1

When appropriate, the clinic is also spacing out supportive therapies such as bone-modifying medications and erythropoiesis-stimulating agents. When pharmacists counsel patients on medication changes, they give them the option of continuing their current regimen/schedule or modifying therapy when feasible, Roman told Drug Topics°.

“This has included spacing out supportive care therapies and occasionally maintenance therapies. In particular, we have done this for agents that have evidence for this approach such as bisphosphonates and immunotherapy,” Roman said. “We have also worked to minimize visits for growth factors based on a patient’s response.”

Roman recommends that oncology pharmacists keep an open line of communication with patients. “If they are unable to come to the clinic in person, we have been reaching out with routine telephone education and follow-up after each cycle. Making sure that patients have support in their home environment has become really important for everyday activities such as grocery shopping, but also for emotional support during this time of isolation,” she said.

Although the clinic is minimizing in-person patient visits, there has been a surge in visits for newly diagnosed malignancies, Roman told Drug Topics°. “In the last several weeks, we have had a record increase in new patients that need anticancer therapy,” she noted. “I can only speculate that this may be related to patients being comfortable seeking medical care and following up on required testing that may not have taken place during the periods of social isolation.”

Results of a study published in JCO Clinical Cancer Informatics that measured the effects of the pandemic on normal cancer care activities showed significant declines in cancer screenings, especially for breast and colorectal cancer, during the height of social distancing. The findings demonstrated declines in mammograms and colorectal cancer screenings in April 2020 compared with April 2019 by 89.2% and 84.5%, respectively. According to the investigators, the data indicate underlying trends observed using diagnosis data and suggested a potential increase in the presentation of later-stage disease for newly diagnosed patients in future months.2

Although the clinic experienced an initial increase in home care/infusion services in the early months of the pandemic, with increased uptake of social distancing and use of personal protective equipment, “we are seeing more patients prefer in-person visits in the clinic,” Roman noted.

However, the clinic continues to use home care services to “help support situations where the patients are not comfortable with the clinic environment or have the need for frequent visits, such as frequent blood draws,” Roman concluded.°

For references, visit drugtopics.com.
The high school football teams in our area are playing football. Only 250 people are allowed in the stands, including the team, coaches, cheerleaders, band, and parents. Everyone is frustrated. Kids have sacrificed their teen years in the weight room, on the practice field, and in the classroom preparing for their time to shine on the gridiron. Risks versus benefits. Kids playing football regularly have risks of concussion, strains, sprains, and broken bones.

To a kid, the risk is worth the benefits of participating in a team sport and possibly getting their chance to be a “star.” Ask any 9th grader’s parents about the benefits of their kid playing football and you will hear in the conversation the chance of a college scholarship.

Our society seems willing to take a risk if it sees benefits. Immunizations, for example, have a very slight risk but great benefit. Antivaxxers focus on the miniscule risks and pay no attention to the benefits. My mom, who had many friends affected by polio in the 1930s and 1940s, marched all 4 of us to the high school to get our dose of Sabin oral polio vaccine when it became available in the early 1960s. Mom knew the benefits.

My dad, a World War II veteran, like millions of others, risked his life for the benefit of his country serving in the US Army. What he witnessed in the European Theater of action, from Northern Africa, Anzio beach, Rome, and Germany was so horrific that he never shared it with his kids. Dad knew the benefits. Back home, the citizens of our country were called upon to ration fuel, sugar, tires, steel, and other necessities for the war effort. A collective effort was made for the common good. They were referred to as the “greatest generation.” The country knew the benefits.

And now, we are asked to wear a cloth face covering, to not only protect ourselves but also to protect others during the coronavirus disease 2019 (COVID-19) pandemic. I work in the pharmacy for nearly 9 hours each day and wear my mask the entire time I’m near anyone. Do the masks help? We got off to a rocky start with masking when the CDC recommended not wearing them in February and early March. On April 24, the CDC officially recommended wearing a mask. However, folks that choose not to wear the mask simply point to the February recommendations.

On the other end of the spectrum are the “mask police,” who want to call out everyone at the pharmacy who removes their mask, even for a brief moment. Yes, one of my customers did that, stating, “The workers could cough and get COVID all over my pills.” The plastic barrier, the sanitizing of the surfaces every hour, and the abundance of hand sanitizer were not enough.

I’d like to offer a proposal to those mask police out there. Whether you are in academia or management, I’d like all licensed pharmacists to join in unity on October 30 to support their brothers and sisters in community pharmacy by wearing a mask for the entire work day. We community pharmacists will even let you take yours off to eat lunch!

“In the absence of rock-solid data to the contrary, wearing a mask seems to be a small sacrifice to protect each other’s health.”

In the absence of rock-solid data to the contrary, wearing a mask seems to be a small sacrifice to protect each other’s health. One of the wiser health care practitioners I work with offered this: “We as a country do not have the collective grit to make large-scale sacrifices for the greater good of the society.” Big benefits… I’m not sure, but definitely a very small risk.

Peter A. Kreckel, RPh, practices community pharmacy in Pennsylvania.
Visit drugtopics.com for an

Get easy access to news, information, practical solutions, trusted perspectives through peer-based forums and opinions.

View in-depth interviews with industry experts.

Find therapeutic and condition-specific information for optimal patient care.

Medical World News®
Discover the 24-hour news channel for #healthcareprofessionals, by health care professionals.

Website Enhancements
• Streamlined navigation, so it is more user-friendly
• Improved mobile compatibility, so it is easier to read on your phone
• Increased responsiveness, so you can find what you are looking for
Enhanced Website Experience

- Use our improved navigation and search.
- Sign up to receive e-newsletters and the print publication.
- Read keynote highlights, industry trends and policy updates.
- Customize content specific to your needs.

Visit drugtopics.com for an easy access to news, information, practical solutions, trusted perspectives through peer-based forums and opinions. View in-depth interviews with industry experts. Find therapeutic and condition-specific information for optimal patient care.

Medical World News®

Discover the 24-hour news channel for healthcare professionals, by healthcare professionals.
Oliceridine (Olinvyk) Offers New Treatment Option for Acute Pain Management in Hospitals and Controlled Clinical Settings

Leah C. Leszczynski, PharmD, and Kevin W. Chamberlin, PharmD, FASCP

Oliceridine (Olinvyk; Trevena, Inc) is an intravenous (IV) opioid agonist indicated in adults for management of acute severe pain in a hospital or controlled clinical setting. Oliceridine should only be used in patients who require an IV opioid analgesic and for whom alternative treatments are inadequate. Oliceridine is a novel µ-opioid receptor ligand with reduced β-arrestin recruitment. β-Arrestin signaling is thought to contribute to opioid-related adverse events (AEs) seen with conventional opioids. Common opioid-related AEs include nausea, vomiting, constipation, and respiratory depression. Oliceridine is intended to be an opioid with an improved respiratory safety profile and reduced incidence of nausea and vomiting. Controlled substance schedule for oliceridine is pending.

The APOLLO-1 and APOLLO-2 trials evaluated the efficacy and safety of oliceridine for acute pain following bunionectomy and abdominoplasty, respectively. In both trials, patients received a loading dose of either placebo, oliceridine (1.5 mg), or morphine (4 mg), followed by demand doses via patient-controlled analgesia (0.1, 0.35, or 0.5 mg oliceridine, 1 mg morphine, or placebo). The primary end point for both trials was the proportion of treatment responders to oliceridine compared with placebo. In APOLLO-1, oliceridine was shown to be an effective analgesic with responder rates of 50%, 62%, and 65.8% in the 0.1 mg, 0.35 mg, and 0.5 mg regimens, respectively, compared with 15.2% for placebo (all *P* < .0001). Oliceridine was also shown to be effective in APOLLO-2 with responder rates of 61%, 76.3%, and 70.0% for 0.1 mg, 0.35 mg, and 0.5 mg regimens, respectively, compared with 45.7% for placebo (all *P* < .05).

In both trials, the composite measure of respiratory safety burden was not statistically different from morphine; however, APOLLO-1 patients in the 0.1-mg and 0.35-mg regimens had a significantly lower risk of experiencing a respiratory safety event when compared with morphine. Of the 3 oliceridine regimens, 0.35 mg and 0.5 mg were shown to be noninferior to morphine at achieving treatment response in both trials.

The most commonly reported AEs for oliceridine were nausea, vomiting, headache, and dizziness. The proportion of patients experiencing 1 or more gastrointestinal-related AEs increased in a dose-dependent manner across the 3 oliceridine regimens. In APOLLO-1, the proportion of gastrointestinal-related AEs ranged from 40.8% to 70.9% in the oliceridine regimens compared with 24.1% for placebo and 72.4% for morphine.

The recommended initial dose is 1.5 mg given IV. Onset of analgesic effect is expected within 2 to 5 minutes after initial dose. Supplemental doses of 0.75 mg can be administered 1 hour after the initial dose and as needed hourly thereafter. For patient-controlled analgesia (PCA), the recommended demand dose is 0.35 mg, with a 6-minute lock out. The cumulative daily dose should not exceed 27 mg due to risk of QT prolongation. Oliceridine 1 mg is approximately equipotent to morphine 5 mg. Oliceridine is available as single-dose 2 mL (1 mg/mL) vials and as 30 mg/30 mL (1 mg/mL) vials for PCA use only.

Patients with decreased cytochrome P450 2D6 function, patients taking a moderate/strong cytochrome P450 3A4 (CYP3A4) inhibitor, or patients who have very recently discontinued a CYP3A4 inducer are at risk of increased plasma concentrations of oliceridine.
FDA Fast Tracks Empagliflozin to Improve Outcomes Following Heart Attack

Officials with the FDA have granted Fast Track designation to empagliflozin (Jardiance; Eli Lilly) to prevent hospitalization for heart failure (HF) and reduce the risk of mortality in patients who have previously had a heart attack.

Empagliflozin is a once-daily tablet currently indicated for use along with diet and exercise to lower blood sugar and reduce risk of cardiovascular (CV) death in adults with type 2 diabetes and known CV disease. The EMPACT-MI phase 3 trial is investigating the effect of empagliflozin on all-cause mortality and hospitalization for HF in adults with and without type 2 diabetes who have had an acute myocardial infarction and no history of chronic HF.

According to Eli Lilly, results from the EMPACT-MI trial are expected in 2023.

Baricitinib Plus Remdesivir Improves Recovery Time for Hospitalized COVID-19

Baricitinib (Olumiant; Eli Lilly) in combination with remdesivir reduced time to recovery in hospitalized patients with coronavirus disease 2019 (COVID-19) when compared with remdesivir, according to initial data from the Adaptive COVID-19 Treatment Trial (ACTT-2).

The phase 3 ACTT-2 trial, which is sponsored by the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health, included more than 1000 patients to assess the efficacy and safety of a 4-mg dose of JAK1/JAK2 inhibitor baricitinib plus antiviral therapy remdesivir versus remdesivir alone in hospitalized patients with COVID-19.

According to the result, study investigators determined an approximate 1-day reduction in median recovery time for the overall patient population treated with baricitinib plus remdesivir versus those treated with remdesivir alone, which was statistically significant.

Based on this data, Eli Lilly plans to discuss the potential for emergency use authorization with the FDA.
YOU’RE TAKING CARE OF YOUR PATIENTS.

IS YOUR PHARMACY SOFTWARE TAKING CARE OF YOU?

99% CUSTOMER SATISFACTION RATING

With 10 full-time, on-staff pharmacists, we get pharmacy. We understand your challenges and are ready to help with outstanding technical assistance and best practice recommendations.

Pharmacy Software helping community pharmacies enhance patient care, increase patient safety, and improve profitability.

View a demo now at www.libertysoftware.com or call us at 800-480-9603

Customer Satisfaction rating from September 2020 customer service survey.
MARKETPLACE

BUY–SELL–BROKER

SELLING YOUR PHARMACY?
ONE FREE PHONE CALL COULD SAVE YOU $300,000 OR MORE.

Do NOT discuss the sale of your pharmacy with a chain, wholesaler, or independent buyer without a free, no obligation consultation.

Get the highest possible price and avoid any unnecessary risks.

✅ Nationwide Representation
✅ Experienced in All Sizes of Transactions and All Buyer Types
✅ Competitive Rates
✅ Licensed and Insured

Daniel J. Lannon, RPh, Broker
Call 888.808.4RPH (4774)
Text 651.769.4932
Email dan@pharmacycbs.com
Web pharmacycbs.com

CONTACTED BY A CHAIN? CALL ME FOR A FREE CONSULTATION.

Drugs Topics

Content Licensing for Every Marketing Strategy

Marketing solutions fit for:
Outdoor
Direct Mail
Print Advertising
Tradeshow/POP Displays
Social Media
Radio & TV

Leverage branded content from Drug Topics® to create a more powerful and sophisticated statement about your product, service, or company in your next marketing campaign.

Contact Eric Temple-Morris to find out more about how we can customize your acknowledgements and recognitions to enhance your marketing strategies.

For information, email Eric Temple-Morris at ETemple-Morris@mmhgroup.com

© 2020 Pharmacy Consulting Broker Services.
Selling Your Pharmacy?
Maximize Your Value
Minimize Your Worry
HAYS LIP & Z OST
Pharmacy Sales Experts Ready to Help You!
www.RxBrokerage.com
Tony Hayslip, ABR/AREP
713-829-7570
Tony@RxBrokerage.com
Ernie Zost, RPH
727-415-3659
Ernie@RxBrokerage.com

Call Hayslip & Zost Pharmacy Brokers LLC for a free consultation. We have helped hundreds of independent pharmacy owners nationwide get the maximum value for their pharmacies. For more information about us, please visit our website.