

PRODUCT PROFILE

XDEMVIY™ lotilaner ophthalmic solution**Manufacturer**

Tarsus Pharmaceuticals, Inc.

Indication

- XDEMVIY is indicated for the treatment of *Demodex* blepharitis.¹

Dosing and Administration

- Instill 1 drop of XDEMVIY in each eye twice daily (approximately 12 hours apart) for 6 weeks. If more than 1 topical ophthalmic drug is being used, the drugs should be administered at least 5 minutes apart. If 1 dose is missed, treatment should continue with the next scheduled dose.¹

Storage and Handling

- XDEMVIY is supplied as a sterile ophthalmic solution in a white, opaque, low-density polyethylene (LDPE) multiple-dose bottle with a LDPE dropper tip and tan high-density polyethylene (HDPE) cap.¹
- Store at 15 °C to 25 °C (59 °F to 77 °F). After opening the XDEMVIY bottle, it can be used until the expiration date on the bottle.¹

Safety/Warnings

- There are no contraindications listed in the prescribing information for XDEMVIY.¹
- Important safety considerations include the risk of contamination and use with contact lenses. Patients should not allow the tip of the dispensing container to contact the eye, surrounding structures, fingers, or any other surface to minimize contamination of the solution. Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions. XDEMVIY contains potassium sorbate, which may discolor soft contact lenses. Contact lenses should be removed prior to instillation of XDEMVIY and may be reinserted 15 minutes following its administration.¹
- The most common ocular adverse reaction observed in controlled clinical studies with XDEMVIY was instillation site stinging and burning which was reported in 10% of patients. Other ocular adverse reactions reported in less than 2% of patients were chalazion/hordeolum and punctate keratitis.¹
- Whereas no overall differences in safety or effectiveness have been observed in patients aged 18 to 65+ years, between elderly and other adult patients, the safety and effectiveness of XDEMVIY in pediatric patients younger than 18 years have not been established.¹

Disease State Background

- *Demodex* blepharitis is an inflammatory eye condition involving the skin, eyelashes, lash follicles, and sebaceous glands.² The disease is associated with infestation with *Demodex* mites—ectoparasites commonly found on human skin.³ Approximately 60% of cases of blepharitis in the United States are associated with *Demodex* mites.^{4,5} Without treatment, *Demodex* blepharitis can lead to more serious corneal conditions that may result in scarring and blindness.^{3,4}

Place in Therapy

- Various management options are utilized for *Demodex* blepharitis. In the absence of clear guidelines or a standard of care, these approaches encompass lid hygiene measures (like cleansing and warm compresses), prescription medications, in-office procedures such as microblepharoexfoliation or intense pulse light, and over-the-counter lid scrubs and wipes containing ingredients like tea tree oil or linalool. However, patient adherence might be affected by associated adverse events and tolerability, and none of these treatments have conclusively demonstrated their effectiveness in fully eradicating mites and eliminating all signs of the disease.⁶⁻¹¹

Managed Care Considerations

- Although the economic impact of Demodex blepharitis is unknown, the results of 1 multicenter study of patients in the United States with confirmed Demodex blepharitis revealed that one-third of patients had visited a medical doctor multiple times in an attempt to alleviate their symptoms, and more than 50% of patients stated they had been experiencing symptoms for at least 4 years.¹² The impact to patient quality of life also can be considerable: 80% of patients shared that the disease negatively affected their activities of daily living (eg, driving at night, daily hygiene routines, and wearing of contact lenses).¹⁵ Average time from onset of symptoms to diagnosis was longer than 1 year, and on average, more than 3 visits to health care providers were needed.¹³ Once diagnosis was established, patients averaged approximately 4 HCP visits per year due to symptoms of *Demodex* blepharitis, with more than 50% of patients stating they visited urgent care, regardless of active disease management. These results highlight the considerable impact of *Demodex* blepharitis and highlight unmet needs in diagnosis and management.^{12,13}

Market Insights

- Demodex blepharitis is a common condition and is caused by a type of mite that lives on the eyelashes and eyelids. Current treatments for demodex blepharitis are often ineffective and can have side effects. An estimated 25 million Americans may have *Demodex* blepharitis.¹⁴
- On July 24, 2023, XDEM VY (lotilaner ophthalmic solution) 0.25% became the first FDA-approved treatment for *Demodex* blepharitis.¹⁵ XDEM VY is the first and only FDA-approved medication that directly targets the Demodex mites that cause the condition.¹⁶
- In clinical trials, XDEM VY was shown to be effective in reducing mite counts and improving symptoms. Important safety considerations include the risk of contamination and use with contact lenses. The safety and effectiveness of XDEM VY have not been established in patients younger than 18 years.
- An estimated 25 million Americans may have *Demodex* blepharitis.¹⁴

REFERENCES

1. XDEM VY. Prescribing information. Tarsus Pharmaceuticals, Inc.; 2023. Accessed August 15, 2023. <https://tarsusrx.com/wp-content/uploads/XDEM VY-Prescribing-Information-24JUL23.pdf>
2. English FP, Nutting WB. Demodicosis of ophthalmic concern. *Am J Ophthalmol*. 1981;91(3):362-372. doi:10.1016/0002-9394(81)90291-9
3. Kheirkhah A, Casas V, Li W, Raju VK, Tseng SC. Corneal manifestations of ocular *Demodex* infestation. *Am J Ophthalmol*. 2007;143(5):743-749. doi:10.1016/j.ajo.2007.01.054
4. Trattler W, Karpecki P, Rapoport Y, et al. The prevalence of *Demodex* blepharitis in US eye care clinic patients as determined by colarettes, a pathognomonic sign. *Clin Ophthalmol*. 2022;16:1153-1164.
5. Teo A, Rosenberg E, Jacobson A. Prevalence of *Demodex* colonization in patients presenting to an outpatient clinic. *Invest Ophthalmol Vis Sci*. 2021;62:1236.
6. Fromstein SR, Harthan JS, Patel J, Opitz DL. *Demodex* blepharitis: clinical perspectives. *Clin Optim (Auckl)*. 2018;10:57-63. doi:10.2147/opto.S142708
7. Clinical management guidelines, blepharitis (lid margin disease). The College of Optometrists. Updated July 7, 2022. Accessed August 15, 2023. https://www.college-optometrists.org/clinical-guidance/clinical-management-guidelines/blepharitis_lidmarginidisease
8. Cheung IMY, Xue AL, Kim A, Ammundsen K, Wang MTM, Craig JP. In vitro antedemodectic effects and terpinen-4-ol content of commercial eyelid cleansers. *Cont Lens Anterior Eye*. 2018;41(6):513-517. doi:10.1016/j.clae.2018.08.003
9. Zhang AC, Muntz A, Wang MTM, et al. Ocular demodex: A systematic review of the clinical literature. *Ophthalmic Physiol Opt*. 2020;40:389-432.
10. Hirsch-Hoffmann S, Kaufmann C, Banninger PB, et al. Treatment options for demodex blepharitis: Patient choice and efficacy. *Klin Monbl Augenheilkd*. 2015;232:384-387.
11. Rhee MK, Yeu E, Barnett M, et al. Demodex blepharitis: a comprehensive review of the disease, current management, and emerging therapies. *Eye Contact Lens*. 2023;49(8):311-318. doi:10.1097/ICL.0000000000001003
12. O'Dell L, Dierker DS, Devries DK, et al. Psychosocial impact of Demodex blepharitis. *Clin Ophthalmol*. 2022;16:2979-2987
13. Ho A, Mun J, Chan A, et al. Characteristics, healthcare resource utilization, and costs among patients with *Demodex* blepharitis: results of a patient survey in the United States. Presented at AMCP 2023; March 21-24, 2023. Accessed August 16, 2023. https://www.jmcp.org/pb-assets/Poster%20Abstract%20Supplements/AMCP%20Abstract%20Supplement%20March%202023_Final-1680576413.pdf
14. Farid M. *Demodex* blepharitis: simple diagnosis, challenging treatment. Digital supplement. *Cataract & Refractive Surgery Today*. Accessed August 16, 2023. <https://crstoday.com/articles/demodex-blepharitis-simple-diagnosis-challenging-treatment/demodex-blepharitis-simple-diagnosis-challenging-treatment/>
15. NDA Approval 217603. Tarsus Pharmaceuticals, Inc. FDA.gov. Published July 24, 2023. Accessed August 16, 2023. https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2023/217603Orig1s000ltr.pdf
16. Tarsus Corporate Presentation. Tarsus Pharmaceuticals, Inc. August 2023. Accessed August 16, 2023. <https://ir.tarsusrx.com/static-files/a4f36edb-9d92-46a2-a8c4-49a3efd6ea94>