

PRODUCT PROFILE

REXULTI *Brexpiprazole tablet*

Manufacturer

Otsuka Pharmaceutical Co, Ltd

Indication

- Rexulti is indicated for:
 - adjunctive treatment of major depressive disorder (MDD) in adults¹;
 - treatment of schizophrenia in adults and pediatric patients 13 years and older²; and
 - treatment of agitation associated with dementia due to Alzheimer disease.¹
- Limitations of use:
 - Rexulti is not indicated as an as-needed treatment for agitation associated with dementia due to Alzheimer disease.¹

Dosing and Administration

- Administer Rexulti orally once daily with or without food.¹
- The recommended starting dosage for the treatment of agitation associated with dementia due to Alzheimer disease is 0.5 mg taken once daily on days 1 to 7. Increase the dosage to 1 mg once daily on days 8 through 14 and to 2 mg once daily on day 15. The recommended target dose is 2 mg once daily. The dosage can be increased to the maximum recommended daily dosage of 3 mg once daily after at least 14 days based on clinical response and tolerability.¹

Storage and Handling

- Rexulti tablets are supplied in bottles of 30 in 0.25-, 0.5-, 1-, 2-, 3-, and 4-mg strengths.¹
- Store Rexulti tablets at 20 to 25 °C (68-77 °F); excursions permitted to 15 to 30 °C (59-86 °F).¹

Safety/Warnings

- Rexulti is contraindicated in patients with a known hypersensitivity to brexpiprazole or any of its components. Reactions have included rash, facial swelling, urticaria, and anaphylaxis.¹
- **BOXED WARNING:** Increased mortality in elderly patients with dementia-related psychosis and suicidal thoughts and behaviors have been noted.¹
 - Elderly patients with dementia-related psychosis who are treated with antipsychotic drugs are at an increased risk of death. Rexulti is not approved for the treatment of patients with dementia-related psychosis without agitation associated with dementia due to Alzheimer disease.¹
 - Antidepressants increased the risk of suicidal thoughts and behaviors in patients 24 years and younger in short-term studies. Monitor closely for clinical worsening and for emergence of suicidal thoughts and behaviors. The safety and effectiveness of Rexulti have not been established in pediatric patients with major depressive disorder.¹
- In clinical trials of adults with agitation associated with dementia due to Alzheimer disease, the most common adverse reactions (with ≥ 4% incidence and at least twice the rate for placebo vs Rexulti) were nasopharyngitis and dizziness.

Disease State Background

- Alzheimer disease
 - Alzheimer disease is an irreversible, progressive neurological condition affecting over 6 million Americans 65 years and older.^{2,3} It is caused by degeneration of neurons and accumulation of abnormal β -amyloid and phosphorylated τ proteins in the brain.⁴ Symptoms include memory loss that disrupts daily life, agitation, changes in sleep patterns, shortened attention span, hallucinations or delusions, and general physical decline.⁵
 - The Agitation Definition Workgroup of the International Psychogeriatric Association (IPA) has defined agitation in Alzheimer dementia (AAD) as⁶:
 - occurring in patients with a cognitive impairment or dementia syndrome;
 - exhibiting behavior consistent with emotional distress, such as excessive motor activity or aggression (physically or verbally);
 - causing excess disability in terms of interpersonal relationships, social functioning, or activities of daily living; and
 - not solely being attributable to another disorder.

Place in Therapy

- Rexulti is the first FDA-approved drug to treat agitation associated with dementia due to Alzheimer disease.³ Based on clinical trials, Rexulti was used with standard Alzheimer disease medications (ie, memantine and donepezil).^{7,8}

Managed Care Considerations

- Agitation can add to the costs of care for an individual with dementia. It is associated with greater direct health care costs and caregiver burden, earlier nursing home placement, and increased morbidity and mortality.^{8,9} The majority of costs are attributed to inpatient hospitalizations and institutionalization.^{8,9}

Market Insights

- Rexulti is the first drug to be FDA approved for the management of agitation associated with dementia due to Alzheimer disease.³

REFERENCES

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