

Rexulti® (brexpiprazole) – Expanded indication

- On December 27, 2021, the <u>FDA approved</u> Otsuka Pharmaceutical's <u>Rexulti (brexpiprazole)</u>, for the treatment of schizophrenia in adults and pediatric patients ages 13 years and older.
 - Rexulti was previously approved for treatment of schizophrenia.
- Rexulti is also approved for adjunctive treatment of major depressive disorder in adults.
- The use of Rexulti in pediatric patients ages 13 years and older is supported by evidence from adequate and well-controlled studies in adults with schizophrenia, pharmacokinetic data from adults and pediatric patients, and safety data in pediatric patients 13 to 17 years of age.
- Rexulti carries a boxed warning for increased mortality in elderly patients with dementia-related psychosis and suicidal thoughts and behaviors.
- The recommended starting dosage for Rexulti for the treatment of schizophrenia in pediatric patients 13 to 17 years of age is 0.5 mg orally once daily on days 1 to 4. The dose should be titrated to 1 mg once daily on day 5 through day 7, then to 2 mg on day 8 based on the patient's clinical response and tolerability. Weekly dose increases can be made in 1 mg increments. The recommended target Rexulti dosage is 2 mg to 4 mg once daily. The maximum recommended daily dosage is 4 mg.
 - Refer to the Rexulti drug label for dosing for its other uses and indications.



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