



## Latuda<sup>®</sup> (lurasidone) – Expanded Indication

- On January 28, 2017, [Sunovion announced](#) the FDA approval of [Latuda \(lurasidone\)](#) for the treatment of adolescent patients aged 13 to 17 years with schizophrenia.
  - Previously, Latuda was only approved for use in adults for the treatment of schizophrenia.
- Latuda is also indicated for monotherapy treatment of adult patients with major depressive episodes associated with bipolar I disorder, and for adjunctive treatment with lithium or valproate in adult patients with major depressive episodes associated with bipolar I disorder.
- Efficacy for the expanded indication of Latuda was established in a 6-week, clinical study of 326 adolescents (13 to 17 years of age) with schizophrenia randomized to 40 mg/day or 80 mg/day of Latuda or placebo.
  - Latuda was superior to placebo in the reduction of Positive and Negative Syndrome Scale scores at week 6 [-8.0 (95% CI: -12.4, -3.7) and -7.7 (95% CI: -12.1, -3.4) placebo-subtracted difference for the 40 mg and 80 mg doses, respectively].
  - On average, the 80 mg/day dose did not provide additional benefit compared to the 40 mg/day dose.
- Latuda carries a boxed warning for increased mortality in elderly patients with dementia-related psychosis, and for suicidal thoughts and behaviors.
- The most common adverse events with Latuda use ( $\geq 5\%$ ) in adolescent patients with schizophrenia were somnolence, nausea, akathisia, extrapyramidal symptoms (non-akathisia), rhinitis/rhinorrhea (80 mg only), and vomiting.
- The recommended starting dose of Latuda in adolescents with schizophrenia is 40 mg orally once daily. Initial dose titration is not required. The maximum recommended dose is 80 mg/day.
  - For the treatment of schizophrenia in adults, the recommended starting dose is 40 mg once daily, with a maximum recommended dose of 160 mg/day.
  - For the treatment of depressive episodes associated with bipolar I disorder, the recommended starting dose is 20 mg once daily as monotherapy or as adjunctive therapy with lithium or valproate. The maximum recommended dose is 120 mg/day.



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