

Seroquel XR® (quetiapine) – First-time Generic

- On November 1, 2016, <u>Par</u> and <u>Accord</u> launched generic versions of AstraZeneca's <u>Seroquel XR</u> (quetiapine) extended-release (ER) tablets.
 - Par launched the 50 mg, 150 mg, 200 mg and 300 mg ER tablets and was granted 180 days of exclusivity.
 - Accord launched the 400 mg ER tablet and was granted 180 days of exclusivity.
- Seroquel XR is indicated for the following:
 - Treatment of schizophrenia
 - Acute treatment of manic or mixed episodes associated with bipolar I disorder, both as monotherapy and as an adjunct to lithium or divalproex
 - Acute treatment of depressive episodes associated with bipolar disorder
 - Maintenance treatment of bipolar I disorder, as an adjunct to lithium or divalproex
 - Adjunctive therapy to antidepressants for the treatment of major depressive disorder
- Seroquel XR carries a boxed warning for increased mortality in elderly patients with dementia-related psychosis, and suicidal thoughts and behaviors.
- According to IMS Health data, U.S. sales of Seroquel XR for the four dosage strengths to be marketed by Par are approximately \$911 million for the 12 months ended September 30, 2016.



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