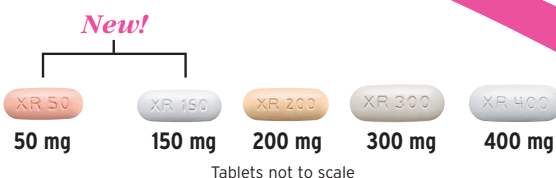


Once-daily
SEROQUEL XR[®]
 quetiapine fumarate
 extended-release tablets
 50, 150, 200, 300 & 400 mg



Dear Pharmacist

AstraZeneca is pleased to introduce two (2) new dosage strengths, SEROQUEL XR 50 mg and 150 mg starting January 12, 2009. SEROQUEL XR is already available in the 200 mg, 300 mg and 400 mg dosage strengths.¹

Important Information

SEROQUEL XR and SEROQUEL are not interchangeable.² SEROQUEL XR once daily is an extended-release formulation that offers continuous drug delivery over the course of the day,^{1,3} while SEROQUEL is an immediate release formulation.⁴

SEROQUEL XR is now the first and only atypical FDA approved for manic, depressive, and mixed episodes of bipolar disorder.⁵

Access

Nationwide, SEROQUEL XR is available to 72% of member lives on Commercial, Medicaid, and Medicare Part D plans with preferred formulary status (Tier 2 or better) without Prior Authorization or Step Edit.^{6,*†}

Please visit www.YourFormularyInfo.com for formulary status for your local plans.[†]

Please update your systems to include SEROQUEL XR 50 mg and 150 mg listed below

Strength	SEROQUEL XR 50 mg		SEROQUEL XR 150 mg	
Size	60 ct bottle	100 ct HUD	60 ct bottle	100 ct HUD
NDC	0310-0280-60	0310-0280-39	0310-0281-60	0310-0281-39

*SEROQUEL XR is available to 73% of member lives on commercial plans (including PBMs, Employer, and Municipal), 60% of member lives on Medicaid (commercial and state), and 86% of member lives on Medicare Part D.

†Individual plan coverage may vary

Important Safety Information for SEROQUEL XR and SEROQUEL

- SEROQUEL XR is indicated for the treatment of acute depressive episodes in bipolar disorder; acute manic or mixed episodes in bipolar I disorder, as either monotherapy or adjunct therapy to lithium or divalproex; maintenance treatment of bipolar I disorder as adjunct therapy to lithium or divalproex; and acute and maintenance treatment of schizophrenia. SEROQUEL is indicated for the treatment of depressive episodes in bipolar disorder; acute manic episodes in bipolar I disorder, as either monotherapy or adjunct therapy to lithium or divalproex; for the maintenance treatment of bipolar I disorder as adjunct therapy to lithium or divalproex; and schizophrenia. Patients should be periodically reassessed to determine the need for continued treatment and the appropriate dose
- Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk (1.6 to 1.7 times) of death, compared to placebo (4.5% vs 2.6%, respectively). SEROQUEL and SEROQUEL XR are not approved for the treatment of patients with dementia-related psychosis (See Boxed Warning)**

Please see additional Important Safety Information on the reverse side and the accompanying full Prescribing Information, including Boxed Warnings.

Additional Important Safety Information for SEROQUEL XR and SEROQUEL

- **Antidepressants increased the risk of suicidal thinking and behavior in children, adolescents, and young adults in short-term studies of major depressive disorder and other psychiatric disorders. Patients of all ages started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. SEROQUEL and SEROQUEL XR are not approved for use in patients under the age of 18 years (See Boxed Warning)**
- Hyperglycemia, in some cases extreme and associated with ketoacidosis, hyperosmolar coma, or death, has been reported in patients treated with atypical antipsychotics, including quetiapine. The relationship of atypical use and glucose abnormalities is complicated by the possibility of increased risk of diabetes in the schizophrenic population and the increasing incidence of diabetes in the general population. However, epidemiological studies suggest an increased risk of treatment-emergent, hyperglycemia-related adverse reactions in patients treated with atypical antipsychotics. Patients starting treatment with atypical antipsychotics who have or are at risk for diabetes should undergo fasting blood glucose testing at the beginning of and periodically during treatment. Patients who develop symptoms of hyperglycemia should also undergo fasting blood glucose testing
- A potentially fatal symptom complex, sometimes referred to as Neuroleptic Malignant Syndrome (NMS), has been reported in association with administration of antipsychotic drugs, including quetiapine. Rare cases of NMS have been reported with quetiapine. Clinical manifestations of NMS are hyperpyrexia, muscle rigidity, altered mental status, and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. The management of NMS should include immediate discontinuation of antipsychotic drugs
- Leukopenia, neutropenia, and agranulocytosis (including fatal cases), have been reported temporally related to atypical antipsychotics, including quetiapine. Patients with a pre-existing low white blood cell (WBC) count or a history of drug-induced leukopenia/neutropenia should have their complete blood count monitored frequently during the first few months of therapy. In these patients, SEROQUEL and SEROQUEL XR should be discontinued at the first sign of a decline in WBC absent other causative factors. Patients with neutropenia should be carefully monitored, and SEROQUEL and SEROQUEL XR should be discontinued in any patient if the absolute neutrophil count is $< 1000/\text{mm}^3$
- Tardive dyskinesia (TD), a potentially irreversible syndrome of involuntary dyskinetic movements, may develop in patients treated with antipsychotic drugs. The risk of developing TD and the likelihood that it will become irreversible are believed to increase as the duration of treatment and total cumulative dose of antipsychotic drugs administered to the patient increase. TD may remit, partially or completely, if antipsychotic treatment is withdrawn. Quetiapine should be prescribed in a manner that is most likely to minimize the occurrence of TD
- Warnings and Precautions also include the risk of orthostatic hypotension, cataracts, seizures, hyperlipidemia, and possibility of suicide attempts. Examination of the lens by methods adequate to detect cataract formation, such as slit lamp exam or other appropriately sensitive methods, is recommended at initiation of treatment or shortly thereafter, and at 6-month intervals during chronic treatment. The possibility of a suicide attempt is inherent in schizophrenia, and close supervision of high risk patients should accompany drug therapy
- The most commonly observed adverse reactions associated with the use of SEROQUEL XR versus placebo in clinical trials for schizophrenia and bipolar disorder were somnolence (25-52% vs 10-13%), dry mouth (12-37% vs 1-7%), constipation (6-10% vs 3-6%), dyspepsia (5-7% vs 1-4%), dizziness (10-13% vs 4-11%), orthostatic hypotension (7% vs 5%), weight gain (7% vs 1%), increased appetite (12% vs 6%), fatigue (6-7% vs 2-4%), dysarthria (5% vs 0%), and nasal congestion (5% vs 1%). The most commonly observed adverse reactions associated with the use of SEROQUEL versus placebo in clinical trials for schizophrenia and bipolar disorder were dry mouth (9%-44% vs 3%-13%), sedation (30% vs 8%), somnolence (18%-34% vs 7%-9%), dizziness (9%-18% vs 5%-7%), constipation (8%-10% vs 3%-5%), asthenia (5%-10% vs 3%-4%), abdominal pain (4%-7% vs 1%-3%), postural hypotension (4%-7% vs 1%-2%), pharyngitis (4%-6% vs 3%), weight gain (5%-6% vs 1%-3%), lethargy (5% vs 2%), nasal congestion (5% vs 3%), SGPT increased (5% vs 1%), and dyspepsia (5%-7% vs 1%-4%)
- In long-term clinical trials of quetiapine, hyperglycemia (fasting glucose ≥ 126 mg/dL) was observed in 10.7% of patients receiving quetiapine (mean exposure 213 days) vs 4.6% in patients receiving placebo (mean exposure 152 days)

Please see accompanying full Prescribing Information, including Boxed Warnings.

References: 1. SEROQUEL XR Prescribing Information. 2. FDA. Electronic Orange Book. <http://www.accessdata.fda.gov/scripts/cder/ob/docs/tempai.cfm>. Accessed January 12, 2009. 3. Data on File 266435, AstraZeneca Pharmaceuticals, LP. 4. SEROQUEL Prescribing Information. 5. Data on File 272661, AstraZeneca Pharmaceuticals, LP. 6. Fingertip Formulary, January 8, 2009.

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