

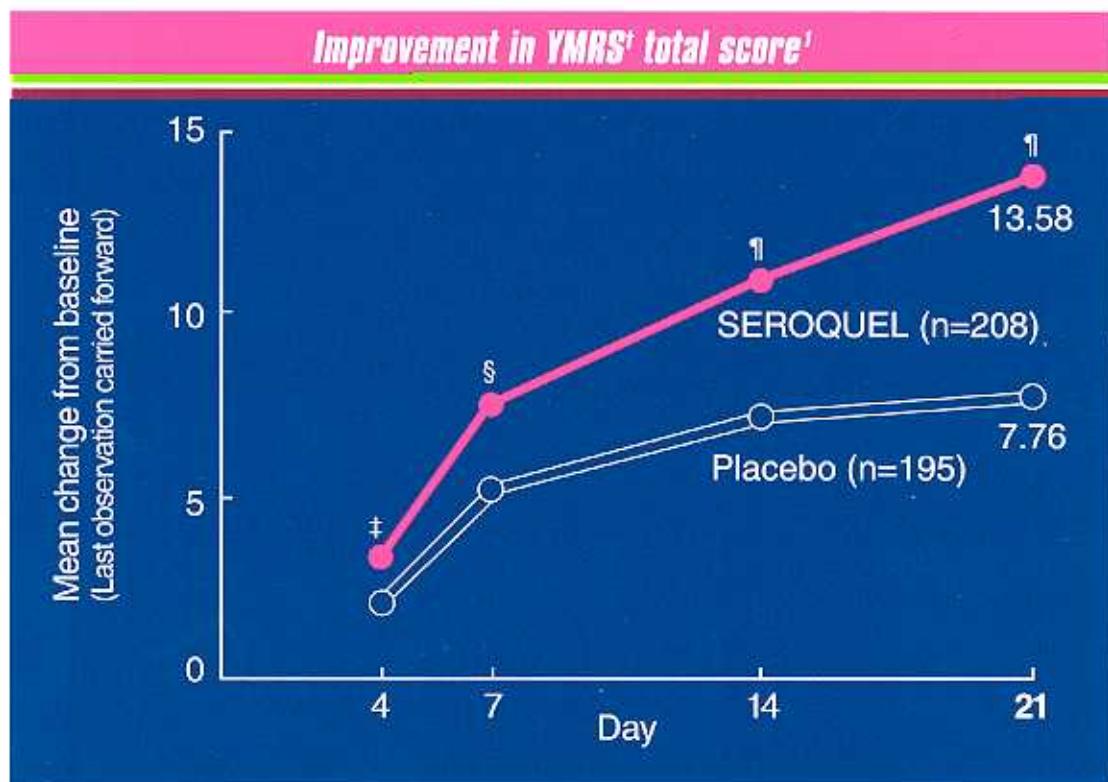
FDA approved for MANIA IN BIPOLAR DISORDER

# Well Accepted!

Average dose in responders\*: 600 mg/day<sup>1</sup>

## Works early<sup>1</sup> in monotherapy...for treatment success

- Statistically significant improvement of manic symptoms as early as Day 4 and at the primary endpoint measured at Day 21 in monotherapy<sup>1</sup>



Data combined from 2 multicenter, randomized, double-blind, placebo-controlled studies as monotherapy in the treatment of mania.  
\*P<0.05 vs placebo. †P<0.01 vs placebo. ‡P<0.001 vs placebo.

## Works across a broad range of mood symptoms<sup>2</sup>...so patients improve

- Statistically significant improvement in **all 11** YMRS items at the primary endpoint measured at Day 21 in monotherapy ( $P \leq 0.007$  vs placebo)<sup>2</sup>

Prescribing should be consistent with the need to minimize the risk of tardive dyskinesia, seizures, and orthostatic hypotension. A rare condition referred to as neuroleptic malignant syndrome (NMS) has been reported with this class of medications, including SEROQUEL.

There have been reports of diabetes mellitus and hyperglycemia-related adverse events associated with the use of atypical antipsychotics, including SEROQUEL.

The most common adverse events associated with the use of SEROQUEL were somnolence, dry mouth, dizziness, constipation, asthenia, abdominal pain, postural hypotension, pharyngitis, SGPT increase, dyspepsia, and weight gain.

<sup>1</sup>Mean last-week median dose in monotherapy mania trials.

<sup>2</sup>Young Mania Rating Scale: an 11-item scale that measures severity of manic symptoms. Four core items (irritability, speech, content, and disruptive/aggressive behavior) were measured on an 8-point scale; the remaining items were measured on a 4-point scale.

Please see accompanying Prescribing Information.

 **Seroquel<sup>®</sup>**  
quetiapine fumarate

25 mg, 100 mg, 200 mg & 300 mg tablets

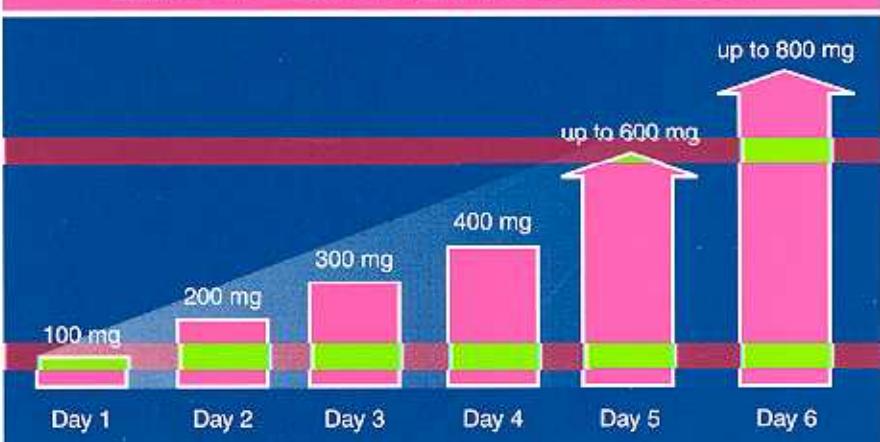
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- In monotherapy trials, >85% of responders<sup>1</sup> received between 400 and 800 mg/day<sup>1</sup>
- The safety of doses above 800 mg/day has not been evaluated in clinical trials<sup>3</sup>

Achieve up to 800 mg/day in less than a week<sup>1,3</sup>



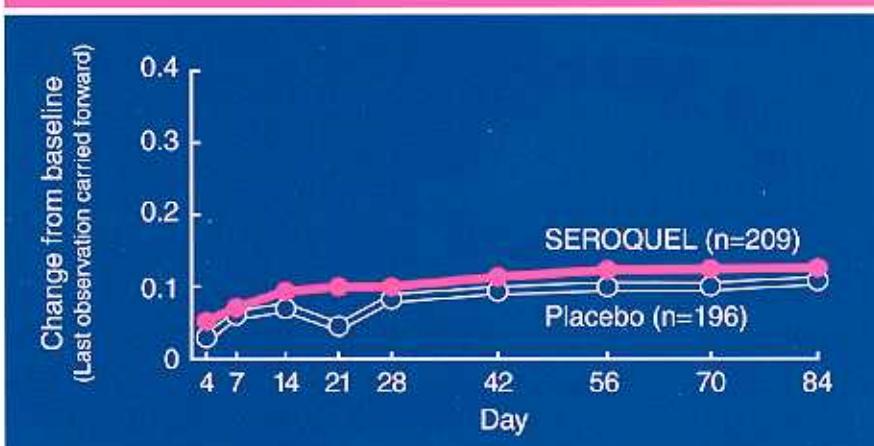
<sup>1</sup> BID dosing.

Trusted tolerability across the dose range<sup>3,4</sup>...so patients can stay on treatment

In monotherapy trials, safety data were assessed at the primary endpoint measured at Day 21 and continued through Day 84

- EPS<sup>5</sup> profile (including akathisia) no different from placebo across the dose range<sup>3,4</sup>
- Serum prolactin levels no different from placebo<sup>3,4</sup>
- Favorable weight profile—average weight gain in monotherapy: 1.8 kg<sup>4</sup>
- Withdrawal rates due to adverse events no different from placebo across the dose range in monotherapy (SEROQUEL 5.7% vs placebo 5.1%)<sup>3</sup>

Improvement in BARS<sup>6</sup> score<sup>4</sup>



Data combined from 2 multicenter, randomized, double-blind, placebo-controlled studies as monotherapy in the treatment of mania.

In the elderly and in patients with hepatic impairment, consideration should be given to a lower starting dose, a slower rate of dose titration, careful monitoring during the initial dosing period, and a lower target dose.

When weight gain was defined as an increase in weight of 7% or more from baseline, there was a significant incidence of weight gain in patients receiving SEROQUEL (21%) vs patients receiving placebo (7%).

SEROQUEL is indicated for the short-term treatment of acute manic episodes associated with bipolar I disorder. Patients should be periodically reassessed to determine the need for continued treatment.

References: 1. Data on file. DA-SER-13; AstraZeneca Pharmaceuticals LP, Wilmington, Delaware. 2. Data on file. DA-SER-18; AstraZeneca Pharmaceuticals LP, Wilmington, Delaware. 3. SEROQUEL<sup>®</sup> (quetiapine fumarate) Prescribing Information, Rev 1/04; AstraZeneca Pharmaceuticals LP, Wilmington, Delaware. 4. Data on file. DA-SLR-14; AstraZeneca Pharmaceuticals LP, Wilmington, Delaware.

To prevent medication errors, write "SEROQUEL" clearly on your Rx pad. Spell "SEROQUEL" clearly over the phone.

**Seroquel<sup>®</sup>**  
quetiapine fumarate  
25 mg, 100 mg, 200 mg & 300 mg tablets

AstraZeneca<sup>®</sup>

AstraZeneca Pharmaceuticals LP  
215186 1/04

<sup>1</sup>Mean last-week median dose in monotherapy mania trials. <sup>2</sup>Patients with 25% improvement in YMRS total score. <sup>3</sup>Extrapyramidal symptoms. <sup>4</sup>Barnes Akathisia Rating Scale, a 4-point scale that assesses the presence and severity of akathisia on a 5-point scale. <sup>5</sup>Last observation carried forward.

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First-line treatment