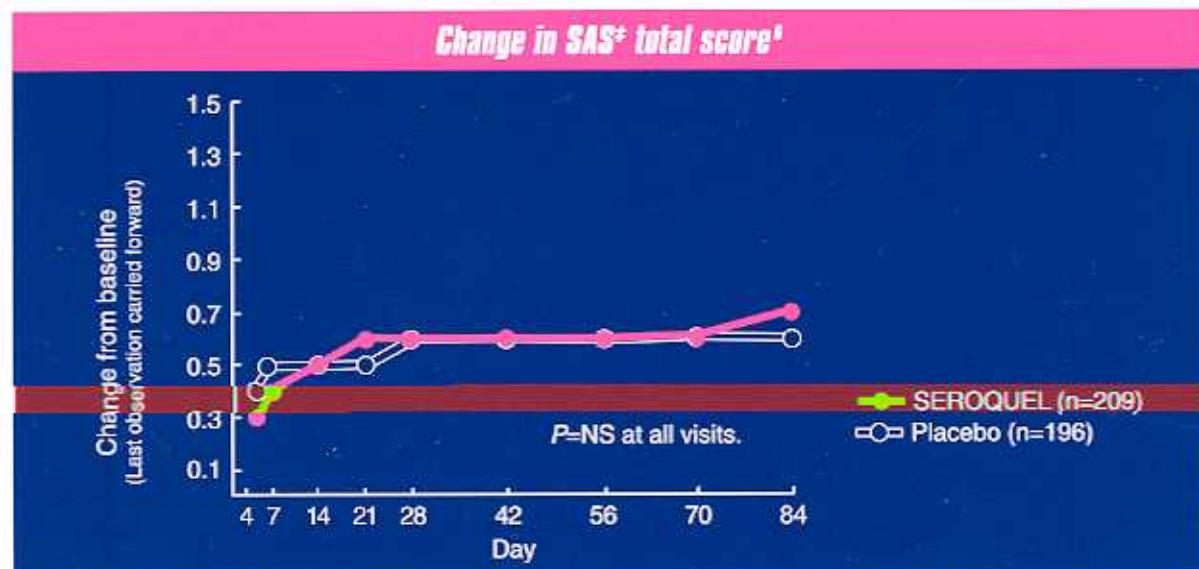




# FOR FIRST-LINE TREATMENT

## Trusted tolerability in bipolar mania<sup>5,7</sup>

- An EPS<sup>1</sup> profile (including parkinsonism) no different from placebo across the dose range<sup>5-7</sup>



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

\*Simpson-Angus Scale: A 10-item scale measuring parkinsonism. Items are rated on a 5-point range (0 to 4) assessing rigidity (7 items), tremor, and salivation.

- Favorable weight profile through Day 84—average weight gain in monotherapy: 1.8 kg<sup>5,6</sup>  
—No withdrawals due to weight gain
- Withdrawal rates due to adverse events were no different from placebo for SEROQUEL as monotherapy (SEROQUEL 5.7%, placebo 5.1%) and adjunct therapy (SEROQUEL plus lithium or divalproex 3.6%, lithium or divalproex alone 5.9%)<sup>5</sup>

<sup>5</sup>SEROQUEL was first approved in 1997 for treatment of schizophrenia and was approved in 2004 for treatment of bipolar mania.

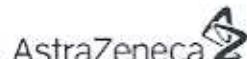
<sup>6</sup>Extrapyramidal symptoms.

<sup>7</sup>Last observation carried forward.

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.

When weight gain was defined as an increase in weight of 7% or more from baseline, there was a statistically 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.



AstraZeneca Pharmaceuticals LP  
21756 1/04

References: 1. Data on file, DA-SER-22, AstraZeneca Pharmaceuticals LP, Wilmington, Delaware. 2. Data on file, DA-SER-18, AstraZeneca Pharmaceuticals LP, Wilmington, Delaware. 3. Data on file, DA-SER-13, AstraZeneca Pharmaceuticals LP, Wilmington, Delaware. 4. Data on file, DA-SER-15, AstraZeneca Pharmaceuticals LP, Wilmington, Delaware. 5. SEROQUEL<sup>®</sup> (quetiapine fumarate) Prescribing Information, Rev 1/04, AstraZeneca Pharmaceuticals LP, Wilmington, Delaware. 6. Data on file, DA-SER-14, AstraZeneca Pharmaceuticals LP, Wilmington, Delaware. 7. Data on file, DA-SER-18, AstraZeneca Pharmaceuticals LP, Wilmington, Delaware.

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Please see accompanying Prescribing Information.

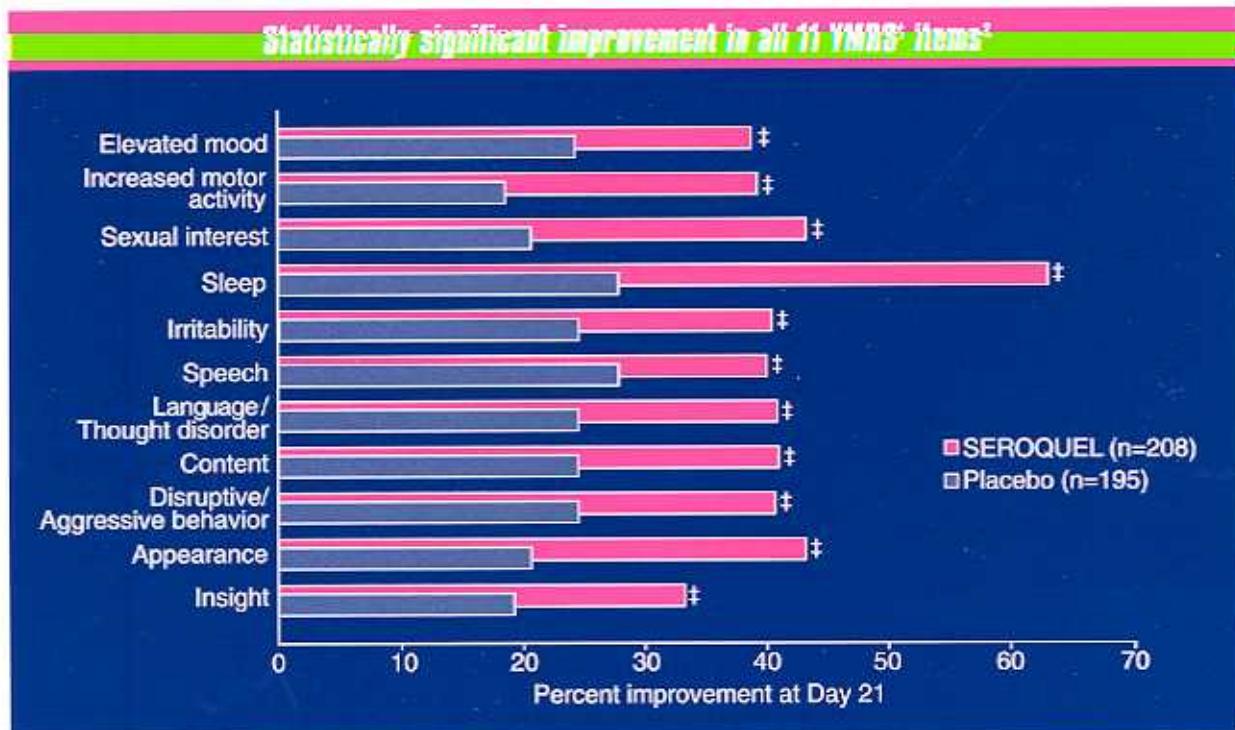
[www.SEROQUEL.com](http://www.SEROQUEL.com)

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



# FOR FIRST-LINE TREATMENT

**Significant improvement over a broad spectrum of symptoms in bipolar mania<sup>2</sup>**



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

<sup>3</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. <sup>1</sup>P<0.007 vs placebo.

- Effectively reduces symptoms of agitation and aggression, as defined by change in PANSS<sup>5</sup> activation subscale score in monotherapy<sup>3</sup>
- Significant improvement of inner tension, reduced sleep, and concentration difficulties was seen, as defined by change in MADRS scores (a scale designed to measure a broad set of mood symptoms)<sup>2</sup>
- Effective as first-line monotherapy and in combination with lithium or divalproex<sup>3,4</sup>

**Average dose in responders<sup>6</sup>: 600 mg/day<sup>2</sup>**

<sup>6</sup>SEROQUEL was first approved in 1997 for treatment of schizophrenia and was approved in 2004 for treatment of bipolar mania.

<sup>1</sup>Positive and Negative Syndrome Scale: a 30-item scale evaluating positive, negative, and other symptoms on a 7-point scale. Most commonly used in schizophrenia.

<sup>2</sup>Mean last-week median dose in monotherapy mania trials.

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 safety of doses above 800 mg/day has not been evaluated in clinical trials. 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.