BRIEF SUMMARY of Prescribing Information—Before prescribing, please consult complete Prescribing Information.

Prescring information.

Increased Motality in Elderly Patients with Dementia-Related Psychosis

Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo, Analyses of seventeen placebo-controlled trials (modal duration of 10 weeks) in these splatients revealed a risk of death in the dep-lated patients of between 1.5 to 1.7 times that seen in placebo-treateg patients. Over the course of a typical tweet controlled trials, the rate of death in drug-related patients was about 4.5%, compared to a rate of about 2.5% in placebo grupp. Although the causes of death were varied, most 10 th deaths appeared to be alther cardiovascular (e), when tallure, usdent death) or infectious (ep, pneumonie) in nature. SERDOUEL (queli-apine) is not approved for the treatment of patients with Dementia-Related Psychosis.

INDICATIONS AND USAGE: Bipolar Mania: SERQUUEL is indicated for the treatment of acute manic episodes asso-rizated with hindar I discorder as either mandiheraby or adjunct therapy to lithium or divalproex. The efficacy of season was usupear i resorrors, as either monotherapy or adjunct therapy to lithium or divalprose. The efficacy of SERODUEL in acrote blood mana was established in his 0.12-week monotherapy that and not 3-week adjunct therapy that of bipodar lipatients mitially hospitalized for up to 7 days from the 18 feet there was his not ober systematically evaluated in chinical trials for more than 12 weeks in monotherapy and 3 weeks in adjunct therapy herefore, the physical who elects to use SERODUEL in exhancing periods should periodically re-evaluate the long-term risks and benefits of the drug for the individual patient. Schlapphrenia SERODUEL is individual patient in Schlapphrenia SERODUEL is individual patient of schlapphrenia. The efficacy of SERODUEL is observably review as well as the properties was scalabled in instruction. Ser SERODUEL for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient. CONTRAINLOCTAINS. SERODUEL is contraindicated in individuals with a known hypersensitivity to this medication or any of its ingredients. ciated with bipolar I disorder, as either monotherapy or adjunct therapy to lithium or diva SERGOUEL in acute bipolar mania was established in two 12-week monotherapy trials and or

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contribute to an elevation in once body temperature, e.g., exercising plenaussiy, apposits to endyration (programma and activations of the activation of the plant activation of the plant activation of the plant activation of the activation of the plant activation of the plant activation of the activation of the plant activation of the activation of the plant activ

SERDOUEL in the elidery compared by puriouse adults. Nevertheless, the presence of factors that might decrease plant-model intellegence, increase the presence of factors that might decrease plant-model intellegence, increase the presence of the state of the part of the presence of the state of the part of

Treatment-Emergent Adverse Experience Incidence in 3- to 12-Week Placebo-Controlled Clinical Trials: for the Treatment of Schizophrenia and Bipater Mania (annotherapy): Body as a Whole: Readchire, Pan. Ashbach. Adcommal Pan. Back Pan. Fore; Cardiovascular Englander. Postural Polycopiestics Dispersive. Dym Mouth. Adcommal Pan. Back Pan. Fore; Cardiovascular Englander. Postural Polycopiestics Dispersive. Dym Mouth. Adcommal Pan. Back Pan. Fore; Cardiovascular Englander. Postural Polycopiestics Dispersion. Power Many Maniationals: Walk Pan. Speri Increased Soff increase. Nerveus: Agathoris. Sometime: Dispersion, Administration Walk Pan. Postural Polycopiestics REACTIONS section reported by patients treated with SEP00LIEL at mutative droses > 7.5 mg/tsq during any phase of a rail within the premarkeding database of approximately 2000 patients treated to shorthorheria. All reported events are included except those already listed in fable 1 or elsewhere in balling, those events for which a drug cause was arrende, and those event error within the wees to general as to be uniformative. It is important to emphasize that although the events reported coursed during freatment with SEP00LIEL, they were not recessarily caused by its definitions. They exert a course of an extra the second of the fabrical properties of the second of the fabrical definitions. They exert a device second of the fabrical definitions is expent a fabrical properties of the second of the fabrical definitions. They exert a fabrical properties of the second of the fabrical devices events are those occurring in the late of 1000 patients (only those not already itself in the labelized results from placebo-controlled that sense occurring in the labelized results in the placebox of the sense occurring in the labelized results in the placebox of the sense occurring in the labelized results in the placebox of the sense occurring in the labelized results in the placebox of the sense occurring in the labelized results in the sense occurring in the labeli Johnson Syndrome (SJS).

DRUG ABUSE AND DEPENDENCE: Controlled Substance Class: SERCQUEL is not a controlled substance. Physical

Johnson Syndrome (S.S.).

PORUR ABUSE AND DEPMODNE: Controlled Substance Class: SEROUBE is not a controlled substance. Physical and Psychologic dependence: SEROUBE, has not been systematically studied, in aimmat for humans for its potential for abuse, tolerance or physical dependence. While the clinical trials do not reveal any lendency for any drug-seeking behavior, these observations were not systematic and it is not possible to predict on the basis of this imideal appearance the extent to which all CNS active drug will be misused, olvertid, and/or abused once marketed. Consequently, behavior, these extents of a SEROUBE, e.g., development of bleares, increases in dose, drug-seeking behavior. Seeking the extent of the seeking of t e until the patient recovers.

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AstraZeneca Pharmaceuticals LP Wilmington, Delaware 19850-5437 Made in USA

I never thought I could be myself again

## Now I can



Now the most prescribed atypical\*

## Proven efficacy To help patients achieve continued success<sup>11-4</sup>

## Trusted tolerability To help patients stay on treatment 1-5

SEROQUEL is indicated for the treatment of acute manic episodes associated with bipolar I disorder, as either monotherapy or adjunct therapy with lithium or divalproex, and the treatment of schizophrenia. Patients should be periodically reassessed to determine the need for continued treatment.

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 is not approved for the treatment of patients with dementia-related psychosis.

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

Hyperglycemia, in some cases extreme and associated with ketoacidosis, hyperosmolar coma, or death, has been reported in patients treated with atypical antipsychotics, including SEROQUEL. 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 during treatment. Patients who develop symptoms of hyperglycemia should also undergo fasting blood glucose testing.

Precautions include the risk of seizures, orthostatic hypotension, and cataract development

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

- All atypical prescriptions: Total prescriptions. Jan. 05-Feb. 06. New prescriptions. Sept. 04-Feb. 06. IMS Health. National Prescription Audit.
- Significant improvement in all 11 YMRS items was measured at Day 21 and continued through Day 84 in monotherapy mania trials.

Please see Brief Summary of Prescribing Information on adjacent page.



Redefine Success

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nei as chizophrenia: onset of action within the first week of treatment. Curr Med Res Opin. 2004;20:1017-1023. 4. Kasper S, Brecher M, Fitton L, et al. Maintenance of long-term efficacy and safety of quetiapine in the open-label treatment of renia. Int Clin Psychopharmacol. 2004;19:281-289. 5. SEROQUEL Prescribing Information.