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

Prescribing information. Increased Mortality in Elderly Patients with Dementia-Related Psychesis Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of leath compared to placebo. Analyses of severeless placebo-controlled risks (modal duration of 10 west) in these patients revealed arisk to death the drug-t-seled patients of between 1.5 to 1.7 times that seen in placebo-treated patients. Over the course of a spical to week controlled tails, the rate of death of they-breated patients was about 1.5%, compared to a rate of about 2.5% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiorescular (e.p. host failure, sudden death) or infectious (e.p. petermola) in nature. SEROQUEL (quetaplies) is not approved for the treatment of patients with Dementia-Related Psychosis.

NOCATIONS AND USAGE: Bipolar Maeia: SEROOUEL is indicated for the treatment of acute manic episodes associated with bipolar I disorder, as either monotheragy or adjunct therapy to lithium or disophrees. The efficacy of SEROOUEL in acute bipolar mania was established in hot 2-week monotherapy to lithium or disophrees. The efficacy of SEROOUEL is not set in monotherapy of a lithium or disophrees that explore against the representable years after in ordinate trains for more than 12 weeks in monotherapy and 3 weeks in adjunct therapy. Therefore, the physician who elects to use SEROOUEL for extended periods should periodically re-evaluate the long-term risks and benefit of the drap for the fruit of the first ordinated the controlled that of schopmenia. The efficacy of SEROOUEL in schopphrenia was established in short-term (f-week) combiled that of schopphrenia praters for the efficacy of SEROOUEL in chapterial school prior land yet enablated the long-term is suffered to the school periorically re-evaluated the long-term subthees of the drup for the individual port and school periorically re-evaluate the long-term subthees of the drup for the individual port of any exhalted the long-term subthees of the drup for the individual port of any of the individual ground in a controlled that of school periorically re-evaluate the long-term subthees of the drup for the individual ground and the school periorically re-evaluate the long-term subthees of the drup for the individual ground and the school periorically re-evaluate the long-term subthees of the drup for the individual ground and the school periorically re-evaluate the long-term subthees of the drup for the individual ground and the school periorically re-evaluate the long-term subthees of the drup for the individual ground and the school periorically re-evaluate the long-term subthees of the drup for the individual ground and the school periorically re-evaluate the long-term subthees of the drup for the individual ground and the school periorically re-evaluate the l

COMPRAMIDICATIONS. SERDOUGL is contraindicated in individuals with a known hypersensitivity to mis measurum or any of its impresentent.

WARRINESS: increased Mortality in Elderly Patients with Dementia-Related Psychosis. Elderly patients with General-related psychosis leader with atypical antipoychic foruga are all encreased its of each compared to placebo. SERDOUEL (questionie) is not approved for the transment of satients with dementia-related personals (see Bound Meming). Nemelogic Malignaria Psychorione (MMS), a potentially tast symptom complex sometimes referred to as Neuroetic Nationari Syndrome (MMS) has been reported in association with administration of antipoycholic durage, including SERDOUEL. Bera cases of MNS have been reported with SERDOUEL (Dirical manifestations of MMS are hypertyrisia; muscle rigidity, altered mental status, and evidence of autonomic instability (impalar pulses nobul pressure, busingerials, diaphores) and carbia eyel mental status, and evidence of autonomic instability of patients with the syndrome is complexated, diaphores, and carbia eyel-influing. Additional signs may may holde elevated creative phosphores, myopiobrusia (Indoorny) and carbie result failure. The diaphoresis evidence for patients with the syndrome is complexated in rainfoy at a diaphosis. In clinical prostration includes both serious medical illness (e.g., pneumoria, systemic infection, etc.) and untritated or rainfoyated variety and prostration of the contral anticohience picto lockoty, host 3 tokes, during been important considerations in the differential diaphores include earthed anticohience picto lockoty, host 3 tokes, during been appropriate prostration creatives system. (NS)

ar indexquality heated eargypramids signs and symptoms (FSS). Other important considerations in the differential depagoes include certal anthoniusery to both, that stokes, drive place and promay extent in errors, septem (FSS), pathoday. The management of MKS should include: I) immediate descrimation of artispyscholar drivag and other drigs not extend to courself therapy; claused symptoms and certain and management courself therapy claused symptoms and pathod strained and pathod some and the courself therapy claused severally considered. The patient advantage of the courself therapy claused severally considered. The patient advantage of the courself therapy claused severally considered. The patient advantage of the courself interest of the symptoms and patient several the pathod severally considered. The patient advantage of the courself interest of the symptoms appointed interests. A symptomic place of the courself of the pathod several courself interests and pathod several the courself of the pathod several courself interests and pathod several the courself of the pathod several courself interests and pathod several courself interests and pathod several courself interests and the courself of the pathod several to the courself of the pathod several courself interests and the courself of the pathod several courself interests and the courself of the pathod several courself interests and the courself of the pathod several courself interests and the courself of the pathod several courself interests and the courself of the pathod several courself interests and the courself of the pathod several courself interests and the courself of the pathod several courself of the pathod several

contribute to an elevation in croit body temperature, e.g., secrosing stremously, apposite to edisperation. Oppolagate: Econyage and antifoliation of the antifoliation of the contribute of the

sis, should lead to consideration of a lower starting dose, slower thratino, and caretum monitoring curring use must use imported in the identy. The mean plasma clearation of SERDOUEL was returned by 30% to 50% in olderly patients when compared to younger patients.

ADVERSE REACTIONS: The information below is defined from a clinical real database for SERDOUEL consisting of over 300 patients. This database includes 405 patients exposed to SERDOUEL for the treatment of acute blocks are in a consistent of the second of the second patients. ADVERSE REACTIONS: The information below is defined from a clinical real database for SERDOUEL consisting of over 300 patients. This database includes 405 patients exposed to 15 move doses of SERDOUEL for the treatment of schropheria. Of these approximately 300 patients approximately 300 patients approximately 300 patients approximately 300 patients. Adversed to 15 move doses of SERDOUEL for the treatment of schropheria. Of these approximately 300 patients approximately 300 patients and processed to 1 move doses of SERDOUEL for the treatment of schropheria. Of these approximately 300 patients approximately 300 patients and schropheria. Adversed to 300 patients approximately 300 patients approximately 300 patients. The schropheria and 300 patients approximately 300 patients approximately 300 patients. The schropheria and 300 patients of schropheria and 300 patients. Adversed to 300 patients approximately 300 patients approximately 300 patients. Adversed 15 schropheria and 300 patients. The patients in 5 schropheria and 300 patients in the schropheria and 300 patients.

Treatment-Emergent Adversa Experience Incidence in 3- to 12-Week Placebo-Controlled Clinical Trials* for the International Controlled Clinical Trials* for the International Clinical Trials* for the Internation Controlled Clinical Trials* for the International Clinical Trials* for the In To rever equivor or to view charmers or wind processes entires. Supplication pages and earlyses in released it plastine tools response process of the control of the contro

Johnson Syndrome (S.S.)

DERICA BUSES AND DEPRICENCE Controlled Substance Class: SEROQUEL is not a controlled substance. Physical and Psychologic dependence: SEROQUEL has not been systematically studied, in animals or humans, for its potential for abuse, theremay on physical dependence. While the clinical tises did not reveal any indensity of any drug-seek-ing betavior, these observations were not systematic and it is not possible to predict on the basis of this limited experience the extent to which a CNS-scribe drug will be mississed, duriend, and as such patients should be evaluated carefully for a history of drug abuse, and such patients should be observed closely for sign of missias or abuse of SEROQUEL i.e., of weekingman for indicance increases in dose, drug-seeking behavior.

DVERDOSAGE: Human experience: Experience with SEROQUEL (quellapine fumantale) in acute overdosage was limited in the clinical intel addabase is reportly with estimated losses ranging from 1000 mp to 9600 mg and no tatalities. In operatin reported signs and symptoms were those resulting from an exapperation of the drug's wown phartness and control of the control of the drug's wown phartness of 19500 mg, was associated with hypoclaemia and first degree heart block in post-marketing experience, there have been very iran reports of overdosa of SEROQUEL cance resulting in ordation. Once see, involving an estimated overdose of 19500 mg, was associated with hypoclaemia and first degree heart block in post-marketing experience, and experience of the operation of the control of the co DRUG ABUSE AND DEPENDENCE: Controlled Substance Class: SEROQUEL is not a controlled substance. Physical additive to those of quetiapine, resulting in problematic hypotension. There is no specific antidote to SEROQUEL. Therefore appropriate supportive measures should be instituted. The possibility of multiple drug involvement should Treation is application as support in resources account on a historia properties and increases and i t recovers. But the AstraZeneca group of companies

Output

Description: SEROQUEL is a n

ca 2004, 2005

AstraZeneca Pharmaceuticals LP Wilmington, Delaware 19850-5437

I never thought I could be myself again

Now I can



Now the most prescribed atypical*

Proven efficacy To help patients achieve continued success¹¹⁻⁴

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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rences: 1. Vieta E, Mullen J, Brecher M, et al. Quetiapine monotherapy for mania associated with bipolar disorder: combined analysis of two international, double-blind, randomised, placebo-controlled studies. Curr Med Res Opin. 2005;21:923-934. chs G, Chengappa KNR, Suppes T, et al. Quetiapine with lithium or divalprosx for the treatment of bipolar mania: a randomized, double-blind, placebo-controlled study. Bipolar Disord. 2004;6:213-223. 3. Small JG, Kolar MC, Kellams JJ. aprine in schizophrenia: 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 ophrenia. Int Clin Psychophramacol. 2004;19:281-289. 6. SEROQUEL Prescribing information.