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

Prescribing information.

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Elderly patients with dementia-related psychosis treated with atypical antipocychotic drugs are at an increased risk of death compared to piscobo. Analyses of seventiene piacebe-controlled trials (model outration of 10 weeks) in these patients revealed arisk of death the drug-traded patients of between 1.5 to 1.7 times that seen in placebo-beated patients. Over the course of a typical 10 week controlled in the control of the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g. host fallows patients was should, exp. penamola) in nature. SEROULEL (quell-apine) is not approved for the treatment of patients with Dementia-Related Psychosis.

MONICATIONS AND MASSEE Byolar Mania: SEROULEL is indicated for the treatment of acute manic episodes asso-ciated with bipolar I disorder, as either monotherapy or adjunct therapy to lithium or divalgnose. The efficacy of SEROULEL in acute bipolar mania was established in No 12-week monotherapy trials and one 3-week adjunct therapy vital or bipolar plants invitally hepolarized for up to 7 of spot and mania; Efficiences has not been systematically evaluated in clinical trials for more than 12 weeks in monotherapy and 3 weeks in adjunct therapy. Therefore, the physican who elects to use SEDOULEL for schooling depricals should periodially re-evaluate more than 12 weeks in monotherapy and 3 weeks in adjunct therapy. Therefore, the physican who elects to use SEDOULEL in schooling pricial short-derived for the treatment of schoolprina. The efficacy of SEOOULEL in schooling was established in short-term 6-weeks to use SEOOULEL for ordinary stream of schoolprinary schooling in schooling and schooling in schooling in schooling and the schooling school pricial school periodical pricial engine for the school pricial school pricial school pricial pr

CONTRAMOLECULOS. SCHOLLES. Contaminatation in individuals with a strone hyperateschildy to this medical or any of La syngratesch public and contract of the co

contribute to an elevation in core body temperature, e.g., exercising chromously, exposure to entreme heat, reconing concentral medication with anticrotherepic activity, or being subject to dishplaction. Pipulapsia: Esological
acces of modelly and orbority in delay pasters, in proficial for the with inforcated Allanders demention.

SERIOUEL and other antispection drugs shared by used contribution to the proficial antispection of the proficial antispection of the proficial antispection of the proficial antispection drugs and proficial antispection of the proficial accompany of the bears contained and proficial accompany of the profic

ss, should lead to consideration of a lower starting does, shower littration, and careful immoring during the imital doesing period in the leichty. The mean joissant edurance of SEROULEL was reduced by 300% to 50% in delethy patients when compared for younger patients.

AUMERSE REACTIONS. The information below is derived from a clinical trial database for SEROULEL consisting of over 3000 patients. This database includes 405 patients exposed to SEROULEL for the treatment of acute bipolar mania (monothersy and adjunct therapy) and approximately 5000 patients approximately 3000 subjects, approximately 2000 (2000 in schizophrenia and 60% in acute bipolar mania (monothersy) and adjunct therapy and adjunct therapy and adjunct therapy and approximately 5000 subjects, approximately 2000 subjects, approximately 2000 (2000 in schizophrenia and 60% in acute bipolar mania (2000 patients) and acute bipolar mania (2000 patients) and adjunction of the schizophrenia (2000 patients) and their experience corresponded to approximately 914.3 patient-years. Refer to the full Prescribing information for details of adverse event data collection. Adverse Friending Sourceward is Start-Term. Custrollar Triats. The start of Start Star

Treatment-Emergent Adverse Experience Incidence in 3- to 12-Week Placebo-Controlled Clinical Trials\* for the Treatment of Schizophrentia and Bipolar Mania (monotherapy): Body as a Whole: Headache, Pain, Asthenia, Addorniral Pain, Back Pain, Fever; Cardinassaular: Tachyaracia, Postural Hypotension: Objective Cry Month, Constitution, Vennting, Dyssepsia, Gottomerientis, Garma Giardamy, Tarasperdates Intrasser Metabolic and Nutritional Weight Gan, SEPT Increased, SGOT Increased. Neurous: Applation, Somoleone, Dizeness, Anelys Respiratory: Pharyonis; Rhintis; Skin and Appendagues: Rach, Special Seasess: Anthypica, Evenis for which the SERCOLEL incidence was equal to or less than placebo are not listed, but included the following, accidental Injury. Treatment of Schlarophrenia and Special Masia (amonotherapy): Body as a White: Instanction, Program Aghoriment, Service Services (Programs Charles), Programs (Special Aghoriment, Charles), Andonomical Programs, Charles, Char

sk, hypotherials, Hacology SS, syntonie on inappropriate altitudined solutions (South, and Severis skins Syntonies on Inappropriate altitudined solutions (SSA).

Althress Syntonies (SSA).

Both SSA (SSA) aumisum symmume (3.35). **Drug abuse and dependence: Controlled Substance Class:** Seroquel is not a controlled substance. **Physical** 

## Two CONTROL CO

## New 50-mg and 400-mg tablets

- 50 mg for simpler dosing during initiation
- 400 mg for an easier way to achieve higher doses\*

- SEROQUEL is indicated for the treatment of acute manic episodes associated with bipolar I disorder, as either monotherapy or adjunct therapy with lithlum 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
  - \*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.
- 'All atypical prescriptions: Total prescriptions. Jan. 05-Dec. 05. New prescriptions. Sept. 04-Dec. 05. IMS Health. National Prescription Audit.

Please see Brief Summary of Prescribing Information on adjacent page.



Tablets shown are not actual size



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