BRIEF SUMMARY of PRESCRIBING INFORMATION
INDICATIONS AND USAGE
SEROQUEL is indicated for the treatment of schizophrenia.
The efficacy of SEROQUEL in schizophrenia was established in short-term (6week) controlled trials of schizophrenic inpatients (See CLINICAL PHARMACDLOGY).
The effectiveness of SEROQUEL in long-term use, that is, for more than 6 weeks,
has not been systematically evaluated in controlled trials. Therefore, the physician
who elects to use SEROQUEL for extended periods should periodically re-evaluate
the long-term usefulness of the drug for the individual patient.
CONTRAINDICATIONS
SEROQUEL is contraindicated in individuals with a known hypersensitivity to this
medication or any of its ingredients.
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Neurolegite Malignant Syndrome: (NMS) A potentially fatal symptom complex sometimes referred to as Neurolegite Malignant Syndrome (NMS) has been reported in association with administration of antipsychotic drugs. Two possible cases of NMS [22837 (17-18)] have been reported in clinical trails with SERDOULEL. Clinical manifestations of NMS are hyperpyrexia, muscle rigidity, altered mental status, and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). Additional signs may include elevated creatine phosphokinase, myoglobinuris (mabdomyolysis) and acute renal failure. The diagnosist ic evaluation of patients with this syndrome is complicated. In arriving at a diagnosis, it is important to exclude cases where the clinical presentation includes both serious medical filmess (e.g., pneumonia, systemic infection, etc.) and untreated or inadequately treated extrapyramidal signs and symptoms (EPS). Other important considerations in the differential diagnosis include central anticholinergic toxicity, heat stroke, drug tever and primary central nervous system (CNS) pathology. The management of NMS should include: 1) immediated discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy. 2) intenses symptomatical regular drugs and serves symptomatical to concurrent therapy. 2) intenses symptomatical during and other symptomatical deconcurrent therapy. considerations in the interestinal diagnosis include central anticholinistic toxicity, heat stroke, drug lever and primary central nervous system (CNS) pathology. The management of NMS should include: 1) immediated iscontinuation of antipsychotic drugs and other drugs not assentiat to concurrent therapy, 2) intenses symptomatic treatment and medical monitoring; and 3) freatment of any concomitant serious medical problems for which specific treatments are available. There is no general agreement about specific pharmacological treatment regiments on NMS englatement of the specific pharmacological treatment regiments on NMS englatement of the specific pharmacological treatment regiments on NMS englatement of the specific pharmacological treatment regiments of NMS in the part of the specific pharmacological treatment regiments on NMS englatement of the specific pharmacological treatment regiments on NMS englatement of the specific pharmacological treatment regiments on NMS englatement of the specific pharmacological treatment regiments on NMS englatement of the specific pharmacological treatment regiments on NMS englatement of the specific pharmacological treatment regiments of the specific pharmacological treatment regiments on the specific pharmacological treatment and the specific pharmacological spec

available or appropriate. In patients who do require chronic treatment, the smallest dose and the shortest duration of treatment producing a satisfactory clinical response should be sought. The need for continued treatment should be reassessed periodically if signs and symptoms of tardive dysfiensia appear in a patient on SEROQUEL, drug discontinuation should be considered. However, some patients may require treatment with SEROQUEL despite the presence of the syndrome. PRECAUTIONS: General Orhobattle Hypotensian: SEROQUEL may induce orthostatic hypotension associated with dizariaes, tachycardia and, in some patients, syncope, especially during the initial obser-furation period, (1226) on placeba and about 0.3% (2426) on active control drugs. The risk of orthostatic hypotension and syncope may be minimized by jurnifulty the initial dose to 25 mg bid. If hypotension occurs during titration to the target dose, a return to the previous dose in the litration schedule sappropriate. SEROQUEL, solvide bused with particular raution in patients with known cardiovascular disease (initiary) of myocardial infrarction or ischemic heart disease, heart failure or conduction abnormalities, Cateractic the development of estarcts was observed in association with quellipsing treatment in bard of salaractic was observed in association with quellipsing treatment in chardiocate and treatment with antilipseriesive medications; Cataractic: the development of salaractic was observed in association with quellipsing treatment in chardiocate and the salaractic disease. Almai Toxicologic patients with patients with patients with a passibility of leafloured the page and the salaractic disease. Almai Toxicologic patients with patients with patients with a passibility of leafloured the patients with a patients with a history of salaract formation, such as still lamp assam or other appropriately assaulties and the patients with a silvent patients with a patients with a patients with a patients with a patient patient patient and maintained witho

SEROULEL® (queltagine furmarate) Tablets
have been associated with antipsychotic drug use. Aspiration pneumonia is a common cause of morbidity and mortality in eliderly patients, in particular those with advanced Atzheimer's dementia. SEROULEL and other antipsychotic drugs should be used cauthously in patients at risk for aspiration pneumonia. Suicide: The possibility of a suicide attempt is inherent in schizophrenia and close supervision of high risk patients should accompany drug therapy. Prescriptions for SEROULEL should be written for the smallest quantity of tablets consistent with good patient management in order to reduce the risk of overdose. Use in Patients with Concomitant Illness: Clinical experience with SEROULEL in patients with certain concomitant systemic litiensess is limited. SEROULEL has not been evaluated or used to any appreciable extent in patients with a recent history of myocardial infarction or unstable heart disease. Patients with these diagnoses were excluded from premarketing clinical studies. Because of the risk of orthostatic hypotension with SEROULEL, caution should be observed in cardiac patients specification of the patients with a recent history of myocardial infarction or unstable uses with patients to whom they prescribe SEROULEL Controlated Hypotension. Patients should be advised of the risk of orthostatic hypotension, especially during the 3-5 day period of initial dose titration, and also at times of re-initiating treatment or increases in dose. Interference with Cognitive and Moter Parlamance. Expression of the proportion of the pr re-initiating treatment or increases in dose, Interference with Cognitive and Moder Performance. She commonive properts devices of the risk of sommonive properts devices of the risk of sommonive properts of the risk of the risk of sommonive properts of the risk of t

Nursing Mothers: SEROULEL, was excreted in milk of treated animals during lactation. It is not known if SEROULEL is excreted in human milk. It is recommended that women receiving SEROULEL is excreted in human milk. It is recommended that women receiving SEROULEL is pediatric patients have not been established. Beriatric Duse: Of the approximately 2400 patients in clinical studies with SEROULEL, 8% (190) were 65 years of age or over. In general, there was no indication of any different tolerability of SEROULEL in the either compared to younger adults. Nevertheless, the presence of factors that might decrease pharmacokinetic clearance, increase the pharmacokymatic response to SEROULEL, or a subsequence or or thotsasis, should lead to consideration of a lower starting dose, slower titration, and careful monitoring during the initial dosing period in the elderty. The mean plasma clearance of SEROULEL was reduced by 30% to 50% in elderly patients when compared to younger patients. younger patients.
ADVERSE REACTIONS

Adverse Frents Cecurring at an Incidence of 1% or More Among SEROQUEL
Treated Patients in Short-Term, Piacebe-Cantrolled Trials: The most commonly
beared adverse events associated with the use of 180 FRQUIDLE (incidence of 1% or
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The most common adverse events associated with the use of SEROQUEL are dizziness (10%), postural hypotension (7%), dry mouth (7%), and dyspepsia (6%). The majority of adverse events are mild or moderate. In 3- to 6-week, placebo-controlled trials, the incidence of somnolence was 18% with SEROQUEL vs 11% with placebo.

As with all antipsychotic medications, prescribing should be consistent with the need to minimize the risk of tardive dyskinesia, seizures, and orthostatic hypotension.

As with all antipsychotic medications, a rare condition referred to as neuroleptic malignant syndrome (NMS) has been reported.

## \*Extrapyramidal symptoms.

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