INDICATIONS AND USAGE
SEROQUEL is indicated for the treatment of schizophrenia.
The efficacy of SEROQUEL in schizophrenia was established in short-term (6-week) controlled trials of schizophrenic inpatients (See CLINICAL PHARMACOLOGY).
The effectiveness of SEROQUEL in long-term use, that is, for more than 6 weeks, as 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 usetilizes of the drug for the individual patient
CONTRAINDICATIONS
SEROQUEL is contraindicated in individuals.

SERCOUEL is contraindicated in individuals with a known hypersensitivity to this mediation or any of its ingredients.

WANNUES

Meurolepite Malignanal Syndrome (MMS) has been reported sometimes reterred to as Neurolepite Malignand Syndrome (MMS) has been reported in association with administration of antispecthord (may, Two possible cases of munifications of MMS are hyperprivate, muscle (apdity, attent). Two possible cases of munifications of MMS are hyperprivate, muscle (apdity, attent) extend status, and evidence of automotic instability (irregular pulse or hoped pressure, tackhyardia, disphoress), and cardiac objestytythmia). Additional signs may include elevated creating dependency and programment of the month of patients with this syndrome is complicated, in arriving at a complex programment of patients with this syndrome is complicated, in arriving at a complex programment of patients with this syndrome is complicated, in arriving at a complex programment of patients with the syndrome is complicated in a mining and the state of the patients of the syndrome is complex programment of the patients of the to an elevation in core body temperature, e.g., exercising strenuously, exposure to extreme heat, receiving concomitant medication with anticholinergic activity, or being subject to dehydration. **Dysphagia**: Esophageal dysmotility and aspiration

have been associated with antipsychotic drug use. Aspiration pneumonia is a common cause of morbidity and mortality in elderly patients, in particular those advanced Alzheimer's dementia. SEROQUEL and other antipsychotic d advanced Azhaimer's dementia. SERQUEL and other antipsychotic drugs advanced Azhaimer's dementia. SERQUEL and other antipsychotic drugs advanced Azhaimer's dementia. SERQUEL and other antipsychotic drugs and several procession of the procession o especially during the 3-5 day period of initial dose infainol, and also at Jirlies of re-initiating freatment of increases in dose, Interference with Cognitive and Moture Performance. Since somnolence was a commonly reported adverse event associated with SCROUCLE, treatment, patients should be advised of the risk of somnolence, especially during the 3-5 day period of initial dose titration. Patients should be advised of the risk and so perating a motor vehicle (including automobiles) or operating hazardous machinery, until they are reasonably certain that SPROUCLE, they goes not affect them adversely. Pregnancy: Patients should be advised to notify their physician if they become pregnant or intend to become pregnant during therapy, Nursing: Patients Should be advised to notify their physicians if they are taking, or plan to take, any present should be advised to notify their physicians if they are taking, or plan to take, any present should be advised to notify their physicians if they are taking, or plan to take, any present should be advised to notify their physicians if they are taking, or plan to take, any present should be advised to provide the properties of the provided the provided them advised to provide the provided them advised to t systematic studies. Given the primary ONS effects of SEROOUEL, caution should be seed when it is taken in combination with other centrally acting orgues. SEROOUEL potentiated the cognitive and motor effects of alcohol in a clinical trial in subjects with selected psycholic disorders, and alcoholic bevergess should be avoided while taking SEROOUEL. Because of its potential for inducing hypotension, SEROOUEL may eithact the effects of reint annihilyperinary langeris. SEROOUEL may antaganize the effects of leventope and disparation of questiganer (250 mp. gibl god pherytom of the effects of the effects

SERVOUBLE\* (questapnie turnarate) labeles

Mursing Mothers: SEROUBLE was excreted in milk of frested animals during lattation. It is not known if SEROUBLE is excreted in human milk. It is recommended that women receiving SEROUBLE should not breast leed. Paghatic Use: The safety and effectiveness of SEROUBLE in pediatinc patients have not been established. Gerhalter described in the service of SEROUBLE in the service of indication of any different tolerability of SEROUBLE in the selective compared to younger adults. Nevertheless, the presence of factors that might decrease pharmacokinetic clearance, increase the other macodynamic response to SEROUBLE. or cause poorer folerance or or or hostsass, should lead to consideration of a lower starting dose, slower litration, and careful monitoring during the initial dosing ceriod in the defent, The mean plasma clearance of SEROUBLE was reduced by 30% to 50% in elderly patients when compared to younger patients. younger patients.
ADVERSE REACTIONS

Adverse Sevents Gecurring at an Incidence of 1% or More Among SEROQUEL
Treated Patients in Short-Term, Placebe-Gontrolled Trials: The most commonly
observed adverse events associated with the use of SEROQUEL (incidence of 5% or
greater) and observed at a rate on SEROQUEL at least living that of placebo warm)
have been adverse preference to the placebo warm of the following treatment-emergent and owns repertience of 1% or more, and were at least as frequent among SEROQUEL treated patients in 3- to 6-week placebo-controlled trials.

Body as a Whote: Headache, Ashtenia, Abdominal pain, Back pain, Fever Nervous System: Somotolence, Discresses, Digestive System; Constipation, Dry Mouth
and Nutritional Biosnfers: Welpit linidence was equal to or less than placebo are not listed in the table, but included the following: pain, intertion, chest pain Instituty, accidental injury, hypertension, busies, comfiring, during myaging agreement of the placebo paint of placebo paint of the placebo paint of placebo paint of placebo paint of the placebo paint of plac

## STRENGTH

to achieve a more normal life

In patients with schizophrenia...

■ SEROQUEL is proven to reduce both positive and negative symptoms1-3

Open-label extension trials suggest that >65% of patients achieve clinical benefit at a dosing range of 400 mg to 800 mg per day4

■ SEROQUEL is the only first-line treatment with an EPS† profile no different from placebo across the entire dosing range<sup>2</sup>

The most common adverse events associated with the use of SEROOUEL are dizziness (10%), postural hypotension (7%), dry mouth (7%), and dyspepsia (6%). The majority of adverse events are mild or moderate.3

As with all antipsychotic medications, prescribing should be consistent with the need to minimize the risk of tardive dyskinesia, seizures, and orthostatic hypotension.3

\*Defined as efficacy to improve the positive and negative symptoms of schizophrenia. †Extrapyramidal symptoms.

References: 1. Small JG, Hirsch SR, Arvanitis LA, et al, and the Seroquel Study Group. Quetiapine in patients with schizophrenia: a high- and low-dose double-blind comparison with placebo. Arch Gen Psychiatry. 1997;54:549-557. 2. Arvanitis LA, Miller BG, and the Seroquel Trial 13 Study Group. Multiple fixed doses of "Seroquel" (quetiapine) in patients with acute exacerbation of schizophrenia: a comparison with haloperidol and placebo. Biol Psychiatry. 1997;42:233-246. 3. SEROQUEL® (quetiapine fumarate) Professional Information Brochure, AstraZeneca Pharmaceuticals LP, Wilmington, Delaware.

4. Data on file, AstraZeneca Pharmaceuticals LP, Wilmington, Delaware.





AstraZeneca Pharmaceuticals LP

© 2001 AstraZeneca Pharmaceuticals LP. SEROQUEL is a registered trademark of the AstraZeneca group of companies.