SEROQUEL® (quetiapine fumarate) Tablets

BRIEF SUMMARY of PRESCRIBING INFORMATION

INDICATIONS AND USAGE Shapes Majain: SEPROUEL is indicated for the short-term treatment of acute manic exposods associated with bigular of domestic as either monotherapy or adjunct therapy to lithium or divalprose. The efficacy of SEROQUEL in acute pinglar mania was established in two 3-week monotherapy trials and one 3-week adjunct therapy risd or bother laptacent similarly hospitalized for up to 7 days for acute main. Efficiences for more than 3-weeks has not been systematically evaluated in clinical trials. Therefore, the physician who elects to use SEROQUEL in extended peniods shouly periodically re-evaluate the long-term insis and benefits of the drug for the individual scient. Schizophrenia: SEROQUEL is indicated for the treatment of schizophrenia. The efficacy of SEROQUEL in indicated for the treatment of schizophrenia was established in short-term (6-week) controlled risids of schizophrenia registeris.

The effectiveness of SEROQUEL in indicated may be useful to the schizophrenia service in a schizophrenia was established in short-term develop to the schizophrenia was established in short-term developed to the schizophrenia was established with a fundicipal was always because the individual patient.

CONTRAINDICATIONS: SEROQUEL is contraindicated in individuals with a known hypersensitivity to this medica

CONTRAMOCATIONS: SEROULE is contrainduced in individuals with a known hypersensitivity to this medication or any of its impedients.

WARRINGS: Neurolegite Malignant Syndroms (NMS): he been propried in association with administration or altripsychic churgs, activities, and a serious propried in association with administration or altripsychic drugs, activities, and a serious propried in association with administration or altripsychic drugs, activities, and a serious propried in association with administration or altripsychic drugs, activities, and a serious propried in a serious propried i although the syndrome may remit, partially or completely, if ambopy-thotic treatment is withdrawn. Analosy-chotic treatment, fiself, however, may suppress (or partially suppress) the signs and symptoms of the syndrome and there by may possibly mask the underlying process. The effect that symptomatic suppression has upon the long-term course of the syndrome is unknown. Given these considerations, SCROUCES, should be prescribed in a manner that course of the syndrome is unknown. Given these considerations, SEFDOUEL, should be prescribed in a manner that is most likely to minimum the occurrence of traftive dyskinesis, Chronic affrages/inch textment should generally be reserved for gatients who appear to suffer from a chronic lifese; bitd (1) is known to respond to artificycholic drogs, and (2) for whom alternative, gough effective, but potentially sea hardful retinations are not availative or appropriate in patients who do require chronic treatment, the smallest dose and the shortest duration of treatment produce as statisticative policies responses should be sought. The need for continued treatment should be reassessed periodically. I signs and symptoms of traffive dyskinesia appear in a patient on SEPDOUEL, drug discontinuation should be considered However, some gatients may require theration with SEPDOUEL diseagle the presence of the syndrome. Hypertypramia and Diabetes Mailitus: Hypertypramia, in some cases extreme and associated with ketacitistics of the syndrome come or each in this bear reported in gatients treated with adjustical straight-cytics, cludding SEPDOUEL. Assessment of the relationship between atypical antisysychotic use and plucose shoromalities is complicated by the possibility of an increased background risk of diabetes meltitis in pleafies with shipporphrenia and between atypical antisysychotic use and hypertypramia-related adverse events is not completely understood. the industry industries of the contraction of the c events in paints' treated with adjustic artisysychorus are not naviation. Presistent with all southern confirmed replication to extend on applicat artisysychorus should be monitored republish for worsening of placuse control. Pallents with risk factors for diabetes mellulus (e.g. obest), tamily instory of diabetes) who are starting treat-ment with applicat analysychorus should underpo starting blood pusce setting in the beginning of treatment and periodically during treatment. Any patient treated with adjustical antisysychorus should be monitored for symptoms of hyperophyrema in landing polydipsis, polydipsis, and weakness. Pallents who develop symptoms of hyperophyrema has researed when the adjustical antisysychorus consistent blood quicose testing, in some cases, hyperophyrema has researed when the adjustical antisysychorus consistent diabetic treatment despite discontinuation of the suspect drong.

periodically during treatment. Any patient treated with altytical antispsychotics should be monitored for symptoms of hyper-glycenes during treatment with altytical artispsychotics should undergo tasking blood glucose stelling, in some easier, perpetyscents have resolved when the aphycical artispsychotics should undergo tasking blood glucose stelling, in some easier and public artispsychotic was observable in the stelling of t

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SEROQUEL® (quetiapine furnarate) Tablets

Set 10.12-Webs Explose-Controlled Clinical Trais's for the Treatment of Schizophrenia and Acute Blockar Mania (monotherapy), Body as a Whate Headstoke, Pan, Astenia, Abdominal Pain, Back Pan, Feere Cardinassalar Ladyracials, Postula Hypostessori, Digisteric by Mouth. Constpain, Monting, Dagose, Gastometric, Garinas Ghamyl, Tradepothese increases, Martines by Martin Cardinas, Monting, 1989, 2018.

Applicable Road, Spatial Sames, Ambroga Estenia Statistical Backgrafter, Plantypic Landston, Soff Increased, Astron. Application, 1999, 2018.

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Steven Johnson syndrome (SJS).

ORNIA BUSIES AND DEPENDENCE: 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, tolerance or objectal dependence. While the clinical tries do not reveal any tendency for any order special pelavoir, these observations were not systematic and is not possible to predict on the basis of the time et experience the extent to which a CNS-active drug will be missed, diverted, and/or abused once marketed. Consequently, patients should be evaluated carefully for a history of drug abuse, and such patients should be conserved closely for signs of misses or abuse of SEROQUEL, e.g., development of followance, increases in dose, drug-seeking behavior.

cosserve closely not signs of malice or abuse of selectivity. E.g., development of interace, increases in obset, of ung-seeking behavior.

**OVERDOSAGE: Human experience: Experience with SEROQUEL (quelspine furnarate) in acute overdosage was limited in the incincul trial distabase (6 reports) with estimated doses ranging from 1200 mg to 9500 mg and no fabilities. In general, reported signs and symptoms were those resulting from an exaggeration of the drugs known pharmacological effects, i.e., drowniness and sestion, hardynardia and hypotension. Die case, involving an estimated overtose of 9500 mg, was associated with hypotelaisma and first degree heart block. In post-marking operations, there have been very rare reports of overdosage, establish and maintain an airway and ensure adequate oxygenation and eventalison. Gastric drowing effective interaction, if patient is unconsciously and administration of activated charcoal together with a laxative should be considered. The possibility of obtundardian control of the patient of the patient is unconsciously and administration of activated charcoal together with a laxative should be considered. The possibility of obtundardiance emiss. Cardiovascular monitoring of beduce possibility of the patient is unconsciously and administration of activated charcoal together with a laxative should be considered. The possibility of obtundardiance emiss. Cardiovascular monitoring of should be made and excit following overdose may create an isst of apprint on with induced emissis. Cardiovascular monitoring of should be considered. The proposition with induced emiss. Cardiovascular monitoring of should be considered. The problematic hypotension has a considered with potential and quintified and patient with an administered of the patient with an administered and patient with an administered and the patient eventual patient excitation. The patient is administered in the patient eventual patient eventual patient eventual and comproperation and control to the cardioval patient and patie

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Manufactured for: AstraZeneca Pharmaceuticals LP Wilmington, Delaware 19850-5437



SEROQUEL is indicated for the treatment of acute manic episodes associated with bipolar I disorder and the treatment of schizophrenia. Patients should be periodically reassessed to determine the need for continued treatment.

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

There have been reports of diabetes mellitus and hyperglycemia-related adverse events associated with the use of atypical antipsychotics, including SEROQUEL.

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.



Redefine Success



AstraZeneca Pharmaceuticals LP

To prevent medication errors, write "SEROQUEL" clearly on your Rx pad. Spell "SEROQUEL" clearly over the phone. www.SEROQUEL.com

Please see Brief Summary of Prescribing Information on following page.