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The International Journal of Neuropsychiatric Medicine

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BRIEF SUMMARY of PRESCRIBING INFORMATION INDICATIONS AND USAGE SEROULEL: sindicated for the treatment of schizophrenia. The efficacy of SEROQUEL in schizophrenia was established in short-term (6 week) controlled trials of schizophrenia invalues (See CLINICAL PHARMACOLOBY) The effectiveness of SEROQUEL in inon-term use, that is, for more than 6 weeks has not been systematically evaluated in controlled trials. Therefore, the physiciar who elects to use SEROQUEL for octanded periods should periodically re-evaluate the ton-term usubliness of the drug for the individual patient. In the other CHITRANDOCATIONS

INTRAINDICATIONS SEROQUEL is contraindicated in individuals with a known hypersensitivity to this edication or any of its ingredients.

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SEROQUEL® (quetiapine fumarate) Tablets

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SEROQUEL® (quetiapine fumarate) Tablets

SERVOYCE: (Quenagine full ratial) radies: Nursing Mohers: SEROULE: we excreted in human milk of treated animals during lacta-tion. It is not known if SEROULE: is excreted in human milk. It is recommended that women receiving SEROULE: subult not breast leade **Pediatric Use:** The safety and effectiveness of SEROULE: in pediatric patients have not been established. **Geniatric** Use: Othe approximately 2400 patients in clinical studies with SEROULE. 8%: (100) were 65 years of age or over. In general, there was no indication of any different tiorability of SEROULE. In the ediderly compared to younger adults. Nevertheless, the presence of factors that might decrease pharmacokinetic clearance. increase the phar-macodynamic response to SEROULEL, to receive porcer tolerance or orthostasis, should lead to cunsideration of a lower starting dose, slower titration, and careful monitoring during the initial dosing period in the edidery. The mean plasma clearance of SEROULE was reduced by 30% to 50% in elderly patients when compared to younger patients.

younger patients. ADVERSE REACTIONS

of SERVUUEL was reduced by 30% to 50% in elderly patients when compared to younger patients. S. AVERSE REACTIONS Adverse Events Docurring at an Incidence of 1% or More Among SEROULEL Treated Patients In Sonri-Term, Placebo-Controlled Triats: The most commonly observed adverse events associated with the use of SEROUCEL (indence of 5% or greater) and observed at a rate on SEROULEL inducence of 5% or greater) and observed at a rate on SEROULEL inducence of 5% or greater) and observed at a rate on SEROULEL inducence of 5%. Or the following treatment-emergent adverse experiences occurred at an incidence of 5% of 1% or more, and were a lease is frequent among SEROULEL (inducence of 5% of 1% or more, and were a lease is frequent among SEROULEL incidence at 5% of 1% or more, and were a lease is frequent among SEROULEL incidence at 5% of 1% or more, and were a lease is frequent among SEROULEL incidence at 5% of 1% or more, and were a lease is frequent among placebo treated patients in Seroir as Cardiovascular System: Rontral hoptension, Tachycardia. Metholic and Mutritional Disorders: Weight gain: Stain and Appendages: Rash, Respiratory System: Ronnolenco, Ibziness: Dispative System: Constituation, Dry Mouth, Drysepsa; Cardiovascular System; Rontral hoptension, Tachycardia. Metholic and Hutritional Disorders: Weight gain: Stain ad Appendages: Rash, Respiratory System: Infinits: Special Bactuate the toais of greater, aga, and race did not reveal any clinically meaningful differences in the adverse event occurrence on the basis of these demographic fractors. Dues Dependency of Adverse Events. Spontaneously elicited adverse event latar rom a study comparing the wide doss of SEROULEL (7, 150, 300, 600, 750 mg/day) to placebo were explored tor coss-relatedness of SEROULEL incidence on adverse revents. Spontaneously elicited adverse event latar rom a study comparing live fixed doss of SEROULEL (7, 150, 300, 600, 750 mg/day) provided evidence for the adv of treatment-emergent etalygrandial syngitone, Hypolation, Hypolenna, five fixed doese of SEROQUEL (75, 150, 300, 600, 750 mg(day) provided evidence for the lax of treatment-mergenet actaryarmalia symptoms (FPS) and Gos-relatedness for FPS associated with SEROQUEL treatment. Three methods were used to measure EPS: (1) Simpson-Angus total Scree (mean change from baseline) which evaluates parkinsonism and akathisia, (2) incidence of spontaneous complaints of FPS (akathisia, akinesia, copyberel ingrify), estranyarmalid syndrome, Hypotenna, Hypoki-nesia, neck rigidity, and termory, and (3) use of anticholinergic medications to treat emergent EPS. In three additional placebo-controlled clinical traits using variable doses of SEROQUEL, there were no differences between the SEROQUEL and placebo treatment groups in the indexine of EPS, as assessed by Simpson-Angus total socials spontameos (FP). With Simp Cammit the SEROQUEL and placebo treatment groups in the indexine of EPS, as assessed by Simpson-Angus total socials spontameos (FP). With Simp Cammit the SEROQUEL is using an anti-toditic hypotension (see PHECAITONES). Weight Weight were compared in a pool of four 3- to 6-week placebo-controlled clinical traits, revealing a statistically significant SEROQUEL supposes than assessment of the prenemetering operinem to SEROQUEL supposes that is associated with asymptomatic increases in SGPT and increases in both total cholescell and trighteemes in the typertraite for capschieradity significant SEROQUELUplacebo ESCOUELL solpestent of table typertraite or tables. ESC Denges: Phareses associated with angus the SEROQUEL and placebo. CEC Denges: Phareses inportant of there as the Net Term, placebo-controlled trials revealed no statistically significant SEROQUELUplacebo CEC Dengeries of placebo. SEROQUEL soperate to a table associated with asymptometer increases of both of SEROQUELUplacebo Centrolled Linical traits revealed no statistically significant SEROQUELUplacebo Centrolled traits revealed no statistically significant SEROQUELUplacebo Centrolled traits revealed no statistically significant abdomen enlarged. Digestive System: Frequent: anorexis, Intrequent: increased salvatoni, increased apatite, gastroenteritis, gastrisis, hemorfnoids, stomattis, thrst, tooth cares, fecal incomence, gastroeschageai rellu, cup memorthage, mouth ulceration, nectal hemorthage, torgue edema, Rare glossitis, hemalemesis, intestinal otstruction, melena, pancratisis, Cardioascular System: Frequent: hapitation, Inferquent vasodilaation, OT interval protonged, migrate, braycardia, cerebral ischemia, irregular pulse, Twave abornamity, bundle branch bock, cerebroxecular accident, deep thrombophebitis, Twave newersion, Rare, angina pectors, atria librillation. 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*Extrapyramidal symptoms

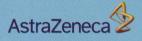
- The most common adverse events associated with the use of SEROQUEL are dizziness (10%), postural hypotension (7%), dry mouth (7%), and dyspepsia (6%). The majority of adverse events are mild or moderate
- As with all antipsychotic medications, prescribing should be consistent with the need to minimize the risk of tardive dyskinesia, seizures, and orthostatic hypotension

Seroquel quetiapine fumarate 25 mg, 100 mg, 200 mg & 300 mg tablets

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Treatment patients can LIVE with!

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. Borison RL, Arvanitis LA, Miller BG. ICI 204,636, an atypical antipsychotic: efficacy and safety in a multicenter, placebo-controlled trial in patients with schizophrenia. *J Clin Psychopharmacol*. 1996;16:158-169. 4. Data on file, Study S91, AstraZeneca Pharmaceuticals LP, Wilmington, Delaware. 5. SEROQUEL* (quetiapine fumarate) Prescribing Information, Rev 1/01, AstraZeneca Pharmaceuticals LP, Wilmington, Delaware.



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