BRIEF SUMMARY of PRESCRIBING INFORMATION
INDICATIONS AND USAGE
SERROUVEL is indicated for the treatment of schizophrenia
The efficacy of SEROOUEL in schizophrenia was established in short-term (6week) controlled risks of schizophrenia inpainters (See CLINICAL PHARMACOLOGY).
The effectiveness of SEROOUEL in long-term use, that is, for more than 6 weeks,
has not been systematically evaluated in controlled traits. Therefore, the physician
who elects to use SEROOUEL for extended periods should periodically re-evaluate
the long-term usefulness of the drug for the individual patient.
CONTRANOICATIONS
SEROOUEL is controlled to individuals with a known hypersensitivity to this
merication or any of its impredients.
WARNINGS
Neuroleptic Malignant Syndrome: (NMS) A patentials fintal generate.

SEROUBLE, is contraindicated in individuals with a known hypersensitivity to this medication or any of its impredients.

WARNINGS

Neuroliptic Malignant Syndrome: (NMS) A potentially fatal symptom complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS) has been reported in association with administration of antipsychotic drugs. Five possible cases of NMS [22387 (17%) have been reported in distinct lariss with SEROUBLE. Directal manifestations of NMS are hyperpress, muscle rigidity, altered mental status, and evidence of autonomic instability (irregular pulse or blood pressure, Endrycardia, disphoress, and cardiac dyshryfirmis). Admitional signs any include elevated creating a continuous status of the status

oose and the should be sought. The need for continued rearment should be reashessed pendically. If signs and symptoms of tarkiev dyshesias appear in a patient on SEROUEL, forgo discontinuation should be considered, however, some patients of the state o

SEROQUEL® (quetiapine fumarate) Tablets

SEROULEL®\* (questiagoine furmariale) Tablets
have been associated with antipsychotic drug use. Aspiration pneumonia is a common
cause of morbidity and mortality in elderly patients, in particular those with
advanced Alzheimer's dementia. SEROULEL and other antipsychotic drugs
should be used cauthously in peleints at risk for aspiration pneumonia. Suicider.
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 rectice the risk of overdose. Use in Patients with
Concomitant Illness: Clinical experience with SEROULEL in patients with certain
concomitant systemic illnesses 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, see Orthostatic
Hypotension, Patients or whom they prescribe SEROULEL, Orthostatic
Hypotension, Patients or the prescribe SEROULEL, Orthostatic
Hypotension, Patients or the risk of orthostate hypotension,
especially during this should be advented of the risk of orthostate hypotension
re-initiating treatment or inorcases in dose, illustrience with Cognitive and Motor
Performance. Since sometime vas a commonly recorded adverse event association. Hypotension). Information for Patients: Physicians are advised to discuss the tollowing issues with patients for whom they prescribe SERQUEL Orthostatic Hypotension: Patients should be advised of the risk of orthostatic hypotension; sepecially during the 3-5 day period of intait does titration. And also at times of a entitlating treatment or increases in does. Interference with Cognitive and Motor Performance: Since somediner was a commonly reported adverse event associated with SERQUEL treatment, patients should be advised of the risk of sommelone, especially during the 3-5 day period of intait does thration. Patients should be autioned about performing any activity requiring merial adminess, such as operating a the property of the patients should be advised to notify their physician if they become preparant or intend to become preparent during therapy Mursing: Patients should be advised not to breast teed if they are taking SERQUEL Concomitant Medication: As with other medications, patients should be advised to avoid consuming achonic beverages while taking SERQUEL had patients should be advised to avoid consuming achonic beverages while taking SERQUEL patients of the patients Adhgsychetic drugs have been shown to chronically elevate prolactin levels in rodents. Serum measurements in a 1-yt rotority study showed that quetapine increased median serum protectin levels a maximum of 32-and 13-fold in male and female rats, respectively. Increases in mammany neoplasms have been found in ordents after chronic administration of other antipsycholic drugs and are considered to be prolactin-mediated mammany oland tumors in rats to human risk is unknown (see hyperprotection-mediated mammany oland tumors in rats to human risk is unknown (see hyperprotection-mediated mammany oland tumors in rats to human risk is unknown (see hyperprotection-mediated mammany oland tumors in rats to human risk is unknown (see hyperprotection-mediated mammany oland tumors in rats to human risk is unknown (see hyperprotection-mediated mammany oland tumors in rats to human risk is unknown (see hyperprotection-mediated mammany oland tumors in rats to human risk is unknown (see hyperprotection-mediated mammany oland tumors in rats to human risk is unknown (see hyperprotection-mediated mammany oland tumors) in rats to human risk is unknown (see hyperprotection-mediated mammany oland tumors) in mamman oland to mamman oland respectively. In the seed of the se SEROQUEL® (quetiapine fumarate) Tablets

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

Adverse Events Occurring at an Incidence of 1% or More Among SEROQUEL Treated Patients in Short-Term, Placebo-Controlled Trials: The most commonly

Treated Patients in Short-Term. Placebe Controlled Trials: The most commonly observed adverse events associated with the use of SPG00UEL (incidence of 5% or greater) and observed at a rate on SER00UEL at least twice that of placebo were obtaineds (10%), postural phypotension (7%), dry month (7%), and dyspession (6%). The following freatment-emergent adverse experiences occurred at an incidence rate of 1% or more. The control of the service of the control of the contr

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## **Editorial Questionnaire**

Your comments are important to us. This form provides you with the opportunity to express your opinions. Our goal is to make *CNS Spectrums* your source for practical and clinical neuropsychiatric information. By filling out this Questionnaire, you enable us to incorporate your views about our editorial content in future issues. Please fill out this form in its entirety. Thank you.

Name (please print)	
Address	
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E-mail Special	ty
Signature	Date
Fax this form to 212-328-0600. Or mail it to: CNS S 333 Hudson Street, 7th Floor, New York, NY 10013	SPECTRUMS, MBL Communications, Inc.,
<ol> <li>On a scale of 1 to 5 (1=Poor, 5=Excellent), please indicate your level of interest and/or satisfaction with the editor content in this issue.</li> <li>Original Research and Review Articles</li> <li>Migraines: Neurological and Psychiatric Perspectives</li> <li>1</li> <li>2</li> <li>3</li> <li>4</li> <li>5</li> </ol>	
Departments Clinical Updates in Neurology  1 2 3 4 5 Clinical Updates in Psychiatry  1 2 3 4 5  CME  1 2 3 4 5  CME  5 CASE Reports	<ul> <li>4. On a scale of 1 to 5 (1=Incomplete, 5=Comprehensive), how would you describe the depth of coverage for this issue?  □ 1 □ 2 □ 3 □ 4 □ 5</li> <li>5. Any other comments about CNS Spectrums' editorial content, design, or overall usefulness?</li> </ul>
□ 1 □ 2 □ 3 □ 4 □ 5  The Neurology of Behavior □ 1 □ 2 □ 3 □ 4 □ 5	
Which areas of neuropsychiatry would you like us to co in the future?	6. Please indicate your title: Psychiatrist Neurologist
Please select any of the following educational materials younged the Composition of the following educational materials younged the Composition of	<ul> <li>Clinical Pocket Reference Guides</li> <li>□ The 2003 Black Book of Psychotropic Dosing and Monitoring</li> <li>□ The Diagnostic and Therapeutic Guide to Sleep Disorders</li> </ul>



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.

References: 1. Small JG, Hirsch SR, Arvanitis LA, et al, and the SEROQUEL Study Group. Quetapine 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 and the U.S. SEROQUEL Study Group. 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 LR Wilmington. Delaware. 5. SEROQUEL." (quetiapine fumarate) Prescribing Information, Rev 1/01, AstraZeneca Pharmaceuticals LP, Wilmington, Delaware. 6. Brecher M. Rak IW. Melvin K., et al. The long-term effect of quetapine (Seroquel") monotherapy on weight in patients with schizophrenia. Int J Psych Clin Pract. 2000;4:287-291. 7. Data on file. DA-SER-02, AstraZeneca Pharmaceuticals LP, Wilmington, Delaware. 8. NPA Plus™ data for dispensed TRxs for the top 3 atypicals (2002 vs 2001). Atypical Market, IMS Amenca, Ltd., 2002. 9. Data on file, DA-SER-10, AstraZeneca Pharmaceuticals LP, Wilmington, Delaware.







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Please see Brief Summary of Prescribing Information on following page.

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