BRIEF SUMMARY of PRESCRIBING INFORMATION INDICATIONS AND USAGE: Bippen Maria: SERVOLEL is indicated for the short-term treatment of acute manic exocutes associated with block i disconta settler manotexpany or adjunct therapy to tithium or diveloptors. The efficacy of SERVOLEL is acute byper manic was established in two 3-week montherapy triats and one 3-week adjunct treatry titls of bipper traditions initially hospitated for up to 7 days for state mania. Effectiveness for more than 3-week has not been systematically excluded in out initial traditions. Therefore, the physical wite elects to use SERVOLEL for extremely and the discute the long-term risks and beenfts of the drug for the individue parterni settlements. Strengthenesis and short the tratement of schedophrenic of schedophrenic traditions. The effectiveness of SERVOLEL in long-term use, that is, for more than 6 weeks, is not been systematically evaluated in controller tains. Therefore, the physica with ore leads to use SERVOLEL for extended periods. Should period law e-evaluate the ion-geterm uses to use SERVOLEL for extended periods. Should period law e-evaluate the ion-geterm use to use SERVOLEL for extended periods. Should period law e-evaluate the ion-geterm uses to use SERVOLEL for extended periods. Should period law e-evaluate the ion-geterm use that there.

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

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Performance of the performance o care is advised while prescripting SEROULE for patients who will be experiencing conditions which may com-tinuble to an event on one obe bydermeature, e.g., exercising stemuously, exposure to extreme heat, receiv-ing concomitant medication with anticholinergic activity, or being solide: to derhydration. *Trypphagita: Escophagel* (spontibility and system) have been advised by the system of the system of the system of the system of the system escope and the system anticholinergic activity or being solide: to derhydration. *Trypphagita: Escophagel* SPROUEL; and other antipsychicit charges should be used: calculatory in patients at tak for saysianton preunonia. Suicide: The possibility of a suicide attempt is interer in hipolar disorder and schizophrenic close supervision of the princip and the system and the system of the system of the system of the singlest quartity of tables consister with poor patient management in order for reduce the risk of orwitches. **Its in Patients** with **Oceanitating the schizophressister** but for substance system clinesses is interf. SEROQUEL and other with these dispension with SEROQUEL, and there and takes the advised system of the results of y division and the and takes. Patient and the advised at the state is a patient of the results of y division and the advised at the state system is with these dispenses were excluded from premar-tering divisial studies. Because of the risk of orthostist hypotension with SEROQUEL, autoin shuld be obsynvel

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SEROOUEL® (quetiagine fumarate) Tablets

Servicus¹ - (Colleague of Total and Processors). **Hormations for Patients:** Physicians are activated to discuss the following spaces with patients for all crosses of the SOULEE. **Orthototic Patients:** Physicians are activated to discuss the following spaces and the processors of the second patient of a crosses of the second patient of the second patient of a crosses of the second patient of the second pati

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Steven Johnson syndrome (S&) DRUG ABUSE AND DEPENDENCE: Controlled Substance Olass: SEPOOUEL is not a controlled substance. Physical and Psychologic Sepondence: SSPOOUEL has not been systemicically studied, in anima's or humans; for its point and to aduse, biosence or hybrical dependence: While the dimit links aid not reveal any tendency for any drag-seiving behavior, these observations were not systemized and it is not possible to predict on the lass of this relation, and were analytication or hybrical dependence. While the dimitised, dimitised, and reveal any tendency for any drag-seiving behavior, these observations were not systemized and it is not possible to predict on the lass of this feature. Consequently, patients should be evaluated caretinit for a history of drug abuse, and such patients should be evaluated caretinity for a history of drug abuse, and such patients should be evaluated careting to rais house not spectra to the observed beasy from the system of the system of more standard beased on the system of the syst

observed toksely for signs of musice of abuse of SERVUUEL e.g., development of toefface, moreases in dose, drug-seeking behavior. OVERDOSHEE: Hennan experience: Experience with SERVOUEL (quetiapine fumarate) in acute overdosage was limited in the inclinal trial database (6 reports) with estimated doses ranging from 1200 rng bo80m gand no fatilities. In general, reported signs and symptoms were those resulting from an exaggeration of the drugs shown pharmacological effects; Le., ovoniess and setabation, radity-carda and hypotension. The case, moving an estimated overdose of 9000 mg, was associated with hypotelerina and first degree heart block. In post-neticing experience, the have been very rare reports of overdosage, stabilish and markatian and administration of activated charcoal together with a laxative should be considered. The possibility of obtained in service adquete overgenation and the ead and nek following overdosage, stabilish and markatian and administration of activated charcoal together with a laxative should be considered. The possibility of obtain-science or quotic versions and a single considered. The possibility of obtain-ticardiorophila and eventogether of the ead and nek following overdosa and should include continuous elec-tocardiorophila and eventogether of SEROULEL. Immitrity any protein single structure (degrup-mide, proclamanide and quindine carry a theoretical hazard of addither UT-prolonging effects when administration there is on specific anticide to SEROULEL. Therefore agruption events that addition theoretical theoret of the addither date of solutional and or symptaminimited apatel tepphine and dopamine should not be used, since bears estimation and versions in the satisfinget measures should be administered and toppartie measures should be administer and tepphinine and dopamine should not be used, since bears estimation may vorsen hypotension in the satisfinget for additioned align utdate is that adm monotroing should channeu with the patient recovers. SEROUCEL is attratemark

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

Rev 01/04

NOW FDA approved for MANIA IN BIPOLAR DISORDER

Vell Accepted

Another great reason to prescribe

• Effective so patients improve¹³

• **Trusted tolerability** so patients can stay on treatment^{1,4,5}

The safety and efficacy of SEROQUEL in pediatric patients have not been established.

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 common adverse events associated with the use of SEROQUEL were somnolence, dry mouth, dizziness, constipation, asthenia, abdominal pain, postural hypotension, pharyngitis, SGPT increase, dyspepsia, and weight gain.

In bipolar mania trials, withdrawal rates due to adverse events were similar to placebo for SEROQUEL as monotherapy (SEROQUEL 5.7%, placebo 5.1%) and adjunct therapy (SEROQUEL plus lithium or divalproex 3.6%, lithium or divalproex alone 5.9%).

References: 1. SEROQUEL[®] (quetiapine fumarate) Prescribing Information, Rev 01/04, AstraZeneca Pharmaceuticals LP, Wilmington, Delaware. 2. Data on file, DA-SER-13, AstraZeneca Pharmaceuticals LP, Wilmington, Delaware. 3. Data on file, DA-SER-15, AstraZeneca Pharmaceuticals LP, Wilmington, Delaware. 4. Data on file, DA-SER-14, AstraZeneca Pharmaceuticals LP, Wilmington, Delaware. 5. Data on file, DA-SER-16, AstraZeneca Pharmaceuticals LP, Wilmington, Delaware.



To prevent medication errors, write "SEROQUEL" clearly on your Rx pad. Spell "SEROQUEL" clearly over the phone. Please see Brief Summary of Prescribing Information on following page.



First-line treatment

AstraZeneca Pharmaceuticals LP 217350 1/04

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