Initial Psych Screenings Key at Nursing Homes

BY KERRI WACHTER Senior Writer

SAN JUAN, P.R. — Consulting psychiatrists can help improve the lives of nursing home residents by establishing psychiatric diagnoses, coordinating medications, and educating staff, Dr. Olivera Bogunovic said at the annual meeting of the American Association for Geriatric Psychiatry.

An estimated 91%-94% of nursing

home residents have some form of psychiatric disorder, said Dr. Bogunovic, professor of psychiatry at the State University of New York at Buffalo. Despite that high prevalence, though, only 2.3% of nursing home residents receive psychiatric consultations.

Consulting psychiatrists, therefore, play an important role in caring for nursing home residents—who are usually managed by internal medicine physicians. Most important, psychiatrists establish a diagnosis, said Dr. Bogunovic, who has also worked as a psychiatric consultant in nursing homes for several years.

Psychiatrists also can assess the interaction between patients with psychiatric disorders and nursing home staff. By educating staff about a patient's condition, psychiatrists can improve general patient care.

In addition, nursing home patients are often taking several medications. "The role of the psychiatrist is to optimize med-

creased Mortality in Elderly Patients with Dementia-Related Psychosis derly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an	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 with advanced Alzheimer's dementia.	Abdominal Pain, Back Pain, Fever; Cardiovascular: Tachycardia, Postural Hypotension; Digestive: Dry Mouth, Constipation, Vomiting, Dyspepsia, Gastroenteritis, Gamma Glutamyl, Transpeptidase Increased; Metabolic and
fery patients with dementia-related psychosis treated with atypical antipsychotic drugs are at a reased risk of death compared to placebo. Analyses of seventeen placebo-controlled trials (modal ration of 10 weeks) in these natients revealed a risk of death in the druc-freated natients of between	SEROQUEL and other antipsychotic drugs should be used cautiously in patients at risk for aspiration pneumonia. Suicide: The possibility of a suicide attempt is inherent in bipolar disorder and schizophrenia; close supervision of	Nutritional: Weight Gain, SGPT Increased, SGOT Increased; Nervous: Agitation, Somnolence, Dizziness, Anxiety; Respiratory: Pharyngitis, Rhinitis; Skin and Appendages: Rash; Special Senses: Amblyopia. ¹ Events for which the
ration of to weeks in unese patients revealed a risk to dealth in the originated patients of device to 1.7 times that seen in placebo-treated patients. Over the course of a typical 10 week controlled 1, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the	high risk patients should accompany drug therapy. Prescriptions for SEROQUEL should be written for the smallest quantity of tablets consistent with good patient management in order to reduce the risk of overdose. Use in Patients	SEROQUEL incidence was equal to or less than placebo are not listed, but included the following: accidental injury, akathisia, chest pain, cough increased, depression, diarrhea, extrapyramidal syndrome, hostility, hypertension,
is die food dealer and generation in the causes of dealth were varied, most of the dealth appeared to be either car- vascular (eg, heart failure, sudden death) or infectious (eg, pneumonia) in nature. SEROQUEL (queti-	with Concomitant Illness: Clinical experience with SEROQUEL in patients with certain concomitant systemic illness- es is limited. SEROQUEL has not been evaluated or used to any appreciable extent in patients with a recent history of userotic indications are used to any appreciable extent in patients with a recent history.	hypertonia, hypotension, increased appetite, infection, insomnia, leukopenia, malaise, nausea, nervousness, pares- thesia, peripheral edema, sweating, tremor, and weight loss. In these studies, the most commonly observed adverse
ne) is not approved for the treatment of patients with Dementia-Related Psychosis.	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 SERQUEL, caution should be observed in car- diac ratients (see Orthostatic Hypotension). Information for Patients: Physicians are advised to discuss the follow	events associated with the use of SEROQUEL (incidence of 5% or greater) and observed at a rate on SEROQUEL at least twice that of placebo were somnolence (18%), dizziness (11%), dry mouth (9%), constipation (8%), SGPT
CATIONS AND USAGE: Bipolar Mania: SEROQUEL is indicated for the treatment of acute manic episodes asso- id with bipolar I disorder, as either monotherapy or adjunct therapy to lithium or divalproex. The efficacy of	the patients (see on ussain representation) in monitoring of patients. Providers are during the order to inscre- ing issues with patients for whom they prescribe SEROQUEL. Orthostatic Hypotension : Patients should be advised of the risk of orthostatic hypotension, especially during the 3-5 day period of initial does titration, and also at times	increased (5%), weight gain (5%), and dyspepsia (5%). Table 2, from the full Prescribing Information, enumerates the incidence, rounded to the nearest percent, of treatment-emergent adverse events that occurred during therapy
ter wind upbear holdstellage states molecularly to adjunct designed relation of the states of the MOULEL in acute bipolar mania was established in two 12-week monotherapy trials and one 3-week adjunct ther- trial of bipolar I patients initially hospitalized for up to 7 days for acute mania. Effectiveness has not been sys-	of the risk of offussion, reportision, especially during the 3-0 day period of initial uses induct, and are sta of re-initiating treatment or increases in does. Interference with Cognitive and Motor Performance: Since somo- lence was a commonly reported adverse event associated with SEROQUEL treatment, patients should be advised of	(up to 3-weeks) of acute mania in 5% or more of patients treated with SEROQUEL (doses ranging from 100 to 800 mg(day) used as adjunct therapy to lithium and divalgroex where the incidence in patients treated with SEROQUEL
atically evaluated in clinical trials for more than 12 weeks in monotherapy and 3 weeks in adjunct therapy. refore, the physician who elects to use SEROQUEL for extended periods should periodically re-evaluate the long-	the isk of commolence, especially during the 3-5 day period of initial does thiration. Patients should be cautioned about performing any activity requiring mental alertness, such as operating a motor vehicle (including automobiles)	was greater than the incidence in placebo-treated patients. Treatment-Emergent Adverse Experience Incidence in 3-Week Placebo-Controlled Clinical Trials' for the Treatment of Bipolar Mania (Adjunct Therapy): Body as a
n risks and benefits of the drug for the individual patient. Schizophrenia: SEROQUEL is indicated for the treat- nt of schizophrenia. The efficacy of SEROQUEL in schizophrenia was established in short-term (6-week) con-	accurate and the second	Whole: Headache, Asthenia, Abdominal Pain, Back Pain; Cardiovascular: Postural Hypotension; Digestive: Dry Mouth, Constipation; Metabolic and Nutritional: Weight Gain; Nervous: Somnolence, Dizziness, Tremor, Agitation;
ed trials of schizophrenic inpatients. The effectiveness of SEROQUEL in long-term use, that is, for more than 6 weeks, not been systematically evaluated in controlled trials. Therefore, the physician who elects to use SEROQUEL for	become pregnant during therapy. Nursing: Patients should be advised not to breast feed if they are taking SEROQUEL Concomitant Medication: As with other medications, patients should be advised to notify their physi-	Respiratory: Pharyngitis: Events for which the SERQUEL incidence was equal to or less than placeboare not list- ed, but included the following: akathisia, diarrhea, insomnia, and nausea. In these studies, the most commonly
ended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient . NTRAINDICATIONS: SEROQUEL is contraindicated in individuals with a known hypersensitivity to this medication	cians if they are taking, or plan to take, any prescription or over-the-counter drugs. Alcohol: Patients should be advised to avoid consuming alcoholic beverages while taking SEROQUEL. Heat Exposure and Dehydration: Patients	b) do and abdoce and another in the set of SEROQUEL (incidence of %% or greater) and observed at a rate on SEROQUEL at least twice that of placebo were somnolence (34%), dry mouth (19%), asthenia (10%), constipa-
my of its ingredients. RNINGS: Increased Mortality in Elderly Patients with Dementia-Related Psychosis: Elderly patients with	should be advised regarding appropriate care in avoiding overheating and dehydration. Laboratory Tests: No specif- ic laboratory tests are recommended. Drug Interactions: The risks of using SEROQUEL in combination with other	bit of roddel: a read whice that of placedo were somethic (9 %), somethic (10 %), somethic
nentia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared placebo. SEROQUEL (quetiapine) is not approved for the treatment of patients with dementia-related psy-	drugs have not been extensively evaluated in systematic studies. Given the primary CNS effects of SEROQUEL, cau- tion should be used when it is taken in combination with other centrally acting drugs. SEROQUEL potentiated the	In interautions of the tasks of genues, age, and tack of only reveal any unitary interaming in memory and any only and a service event occurrence on the basis of these demographic factors. Dose Dependency of Adverse Events is Nont-Term, Placebo-Controlled Trials: Dose-related Adverse Events: Spontaneously elicited adverse event data from a study of
sis (see Boxed Warning). Neuroleptic Malignant Syndrome (NMS). A potentially fatal symptom complex some- es referred to as Neuroleptic Malignant Syndrome (NMS) has been reported in association with administration of	cognitive and motor effects of alcohol in a clinical trial in subjects with selected psychotic disorders, and alcoholic beverages should be avoided while taking SEROQUEL. Because of its potential for inducing hypotension, SEROQUEL	rate or comparing the fixed doese of SEROQUEL (75 mg, 150 mg, 300 mg, 600 mg, and 750 mg/day) to place- bo were explored for does-relatedness of adverse events. Logistic regression analyses revealed a positive does
psychotic drugs, including SEROQUEL. Rare cases of NMS have been reported with SEROQUEL. Clinical mani- ations of NMS are hyperpyrexia, muscle rigidity, altered mental status, and evidence of autonomic instability	may enhance the effects of certain antihypertensive agents. SEROQUEL may antagonize the effects of levodopa and dopamine agonists. The Effect of Other Drugs on Quetiapine: Phenytoin: Coadministration of quetiapine (250 mg	be verse explored or doceretainabilities or adverse events: cogression regressions (p.ed.0.5) for the following adverse vents: dyspepsia, abdomiral pain, and veging dain. Extragyramidal Symptoms: Data from one 6-week clinical trial of schizophrenia comparing five fixed doses of SEROQUEL (75, 150, 300,
egular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). Additional signs may include rated creatine phosphokinase, myoglobinuria (rhabdomyolysis) and acute renal failure. The diagnostic evaluation additional with the surgificant of a gradient of a discrete size of the surgificant of the surgificant of the surgificant of a discrete size of the	tid) and phenytoin (100 mg tid) increased the mean oral clearance of quetiapine by 5-fold. Increased doses of SEROQUEL may be required to maintain control of symptoms of schizophrenia in patients receiving quetiapine and	600, 750 mg/day) provided evidence for the lack of treatment-emergent extrapyramidal symptoms (EPS) and dose-
valents with this syndrome is complicated. In arriving at a diagnosis, it is important to exclude cases where the ical presentation includes both serious medicial illness (e.g., pneumonia, systemic infection, etc.) and untreated madequately treated extrapyramidal signs and symptoms (EPS). Other important considerations in the differential	pherytoin, or other hepatic enzyme inducers (e.g., carbamazepine, barbiturates, rifampin, glucocorticoids). Caution should be taken if pherytoin is withdrawn and replaced with a non-inducer (e.g., valproate). Divalproex:	relatedness for EPS associated with SEROQUEL treatment. Three methods were used to measure EPS: (1) Simpson- Angus total score (mean change from baseline) which evaluates parkinsonism and akathisia, (2) incidence of sponta- neouse completed EDE (change from baseline) which evaluates parkinsonism and akathisia, (2) incidence of sponta- neouse completed end to the evaluate of the change of the evaluates of the evaluate of the evaluates of the evaluates of the evaluate of the evaluates of the eval
naced and the management of NMS should include: 1) immediate discontinuation of anticescharter (NS) holow. The management of NMS should include: 1) immediate discontinuation of anticeschotic drues and other	Coadministration of quetiapine (150 mg bid) and divalproex (500 mg bid) increased the mean maximum plasma con- centration of quetiapine at steady-state by 17% without affecting the extent of absorption or mean oral clearance.	neous complaints of EPS (alatitisia, akinesia, cogwheel rigidity, extrapyramidal syndrome, hypertonia, hypokinesia, neck rigidity, and tremori), and (3) use of anticholinergic medications to treat emergent EPS. Vital Signs and Laboratory Studies: Vital Sign Changes: SEROUCLE is associated with orthostatic hypotension (see PRECAUTIOR).
is not essential to concurrent therapy; 2) intensive symptomatic treatment and medical monitoring; and 3) treat- nt of any concomitant serious medical problems for which specific treatments are available. There is no general	Thioridazine: Thioridazine (200 mg bid) increased the oral clearance of quetiapine (300 mg bid) by 65%. Cimetidine: Administration of multiple daily doese of cimetidine (400 mg bid for 4 days) resulted in a 20% decrease in the mean and decrement of audiopine (160 mg bid). Decrease of increment for audiopine, near the output his mean with cime	Weight Gain: In schizophrenia trials the proportions of patients meeting a weight gain criterion of ≥7% of body weight
eement about specific pharmacological treatment regimens for NMS. If a patient requires antipsychotic drug trment after recovery from NMS, the potential reintroduction of drug therapy should be carefully considered. The	oral clearance of quetapine (150 mg tid). Dosage adjustment for quetapine is not required when it is given with char- tidine. P450 3A Inhibitors: Coadministration of ketoconazole (200 mg once daily for 4 days), a potent inhibitor of cytochrome P450 3A, reduced oral clearance of quetapine by 84%, resulting in a 335% increase in maximum plas-	were compared in a pool of four 3- to 6-week placebo-controlled clinical triats, revealing a statistically significantly greater incidence of weight gain for SEROQUEL (23%) compared to placebo (6%). In mania monotherapy triats the proportions of patients meeting the same weight gain criterion were 21% compared to 7% for placebo and in mania
ent should be carefully monitored since recurrences of NMS have been reported. Tardive Dyskinesia: A syn- me of potentially irreversible, involuntary, dyskinetic movements may develop in patients treated with antipsy-	cytochronie P4O SA, reduced dra clearance or queriagnie by 64%, resulting in a 355% increase in instantian bas- ma concentration of quetiapine. Caution is indicated when SERQOUEL is administered with ketoconazole and other inhibitors of cytochrome P450 SA (e.g., itraconazole, fluconazole, and evthromycin). Fluoxetine, Imigramine,	adjunct therapy trials the proportion of patients meeting the same weight criterion were 13% compared to 4% for
tic drugs. Although the prevalence of the syndrome appears to be highest among the elderly, especially elderly men, it is impossible to rely upon prevalence estimates to predict, at the inception of antipsychotic treatment,	Haloperidol, and Risperidone: Coadministration of fluxotelic (60 mg once daily); imipramine (75 mg bid), haloperid dol (7.5 mg bid), or risperidone: Coadministration of fluxotelic (60 mg once daily); imipramine (75 mg bid), haloperid dol (7.5 mg bid), or risperidone (3 mg bid) with quetiapine (300 mg bid) did not after the steady-state pharmacoki	placebo. Laboratory Changes: An assessment of the premarketing experience for SEROQUEL suggested that it is associated with asymptomatic increases in SBPT and increases in both total cholesterol and triglycerides (see PRE- CAUTIONE). As accompared to the metabolish expension of the contract term checked experience of the contract o
ch patients are likely to develop the syndrome. Whether antipsychotic drug products differ in their potential to se tardive dyskinesia is unknown. The risk of developing tardive dyskinesia and the likelihood that it will become	netics of quetiapine. Effect of Quetiapine on Other Drugs: Lorazepam: The mean oral clearance of lorazepam (2 mg, single dose) was reduced by 20% in the presence of quetiapine administered as 250 mg tid dosing. Divalproex: The	CAUTIONS). An assessment of hematological parameters in short-term, placebo-controlled trials revealed no clinical- ly important differences between SEROQUEL and placebo. ECC Changes: Between group comparisons for pooled clacks acettricated and an activiticity invited to ECONUEL folgeboard differences in the parameters of the paramet
versible are believed to increase as the duration of treatment and the total cumulative dose of antipsychotic drugs ninistered to the patient increase. However, the syndrome can develop, although much less commonly, after rel-	mean maximum concentration and extent of absorption of total and free valproic acid at steady-state were decreased by 10 to 12% when divalproex (500 mg bid) was administered with quetiapine (150 mg bid). The mean oral clear-	placebo-controlled trials revealed no statistically significant SEROQUEL/placebo differences in the proportions of patients experiencing potentially important changes in ECG parameters, including 0.1, 0.1c, and PR intervals. However, the approximate of experience provides the order of tradeword in wave expension of low 2, a for wave a locate controlled intervals. The second
ely brief treatment periods at low doses. There is no known treatment for established cases of tardive dyskinesia, ough the syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn. Antipsychotic treatment is withdrawn. Antipsychotic treatment is withdrawn.	ance of total valproic acid (administered as divalproex 500 mg bid) was increased by 11% in the presence of queti- apine (150 mg bid). The changes were not significant. Lithium: Concomitant administration of quetiapine (250 mg	the proportions of patients meeting the criteria for tachycardia were compared in four 3- to 6-week placebo-controlled clinical trials for the treatment of schizophrenia revealing a 1% (4/39) incidence for SEROULEL compared to 0.6% (4/50) incidence for schizophrenia meeting and the providence for schizophrenia to the schizophrenia for the treatment of schizophrenia the schizophrenia for the
tment, itself, however, may suppress (or partially suppress) the signs and symptoms of the syndrome and there- may possibly mask the underlying process. The effect that symptomatic suppression has upon the long-term may drive any drown is undergoing to suppress the syndrome statement of the syndrome structure of the syndrome is undergoing and the syndrome structure of the syndrome is undergoing the syndrome structure of the sy	tid) with lithium had no effect on any of the steady-state pharmacokinetic parameters of lithium. Antipyrine: Administration of multiple daily doses up to 750 mg/day (on a tid schedule) of quetiapine to subjects with selected	(1/156) incidence for placebo. In acute (monotherapy) bipolar mania trials the proportions of patients meeting the cri- teria for tachycardia was 0.5% (1/192) for SERODUEL compared to 0% (0/178) incidence for placebo. In acute bipo- termatic diversity with the bit of the second sec
rsé ôf the syndrome is unknown. Given these considerations, SEROQUEL shoùid be prescribéd in a mannér that nost likely to minimize the occurrence of tardive dyskinesia. Chronic antipsychotic treatment should generally be evred for patients who appear to suffer from a chronic illness that (1) is known to respond to antipsychotic drugs.	psychotic disorders had no clinically relevant effect on the clearance of antipyrine or urinary recovery of antipyrine metabolites. These results indicate that quetiapine does not significantly induce hepatic enzymes responsible for	lar mania (adjunct) trials the proportions of patients meeting the same criteria was 0.6% (1/166) for SEROQUEL com- pared to 0% (0/171) incidence for placebo. SEROQUEL use was associated with a mean increase in heart rate,
(2) for whom alternative, equally effective, but potentially less harmful treatments are not available or appropri- in patients who do require chronic treatment, the smallest dose and the shortest duration of treatment produc-	cytochrome P450 mediated metabolism of antipyrine. Carcinogenesis, Mutagenesis, Impairment of Fertility: Carcinogenesis: Carcinogenicity studies were conducted in C57BL mice and Wistar rats. Quetapine was adminis-	assessed by ECG, of 7 beats per minute compared to a mean increase of 1 beat per minute among placebo patients. This slight tendency to tachycardia may be related to SEROQUEL's potential for inducing orthostatic changes (see PRE-
In patients who do require criteria learning, he smallest does not the interest dorated of reaming podder a satisfactory clinical response should be sought. The need for continued treatment should be reassessed peri- cally. If signs and symptoms of tardive dyskinesia appear in a patient on SEROQUEL, drug discontinuation should	tered in the diet to mice at doses of 20, 75, 250, and 750 mg/kg and to rats by gavage at doses of 25, 75, and 250 mg/kg for two years. These doses are equivalent to 0.1, 0.5, 1.5, and 4.5 times the maximum human dose	CAUTIONS). Other Adverse Events Observed During the Pre-Marketing Evaluation of SEROQUEL: Following is a list of COSTART terms that reflect treatment-emergent adverse events as defined in the introduction to the ADVERSE
considered. However, some patients may require treatment with SEROOUEL despite the presence of the syndrome. herglycemia and Diabetes Mellitus: Hyperglycemia, in some cases extreme and associated with ketoacidosis or	(800 mg/day) on a mg/m ² basis (mice) or 0.3, 0.9, and 3.0 times the maximum human dose on a mg/m ² basis (rats). There were statistically significant increases in thyroid gland follicular adenomas in male mice at doses of 250 mg/m ² basis at dose basis at doses of 250 mg/m ² basis at dose basis at doses of 250 mg/m ² basis at dose basis at doses of 250 mg/m ² basis at dose basis at	REACTIONS section reported by patients treated with SEROQUEL at multiple doses \geq 75 mg/day during any phase of a trial within the premarketing database of approximately 2200 patients treated for schizophrenia. All reported events
erosmolar coma or death, has been reported in patients treated with atypical antipsychotics, including SEROQUEL, essment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the	and 750 mg/kg or 1.5 and 4.5 times the maximum human dose on a mg/m² basis and in male rats at a dose of 250 mg/kg or 3.0 times the maximum human dose on a mg/m² basis. Mammary gland adenocarinomas were sta- tistically adjusted to function the deliverse that deliverse the dot 250 mg/m² basis.	are included except those already listed in Table 1 or elsewhere in labeling, those events for which a drug cause was remote, and those event terms which were so general as to be uninformative. It is important to emphasize that,
sibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing inci- ce of diabetes mellitus in the general population. Given these confounders, the relationship between atypical	tistically significantly increased in female rats at all doses tested (25, 75, and 250 mg/kg or 0.3, 0.9, and 3.0 times the maximum recommended human dose on a mg/m ² basis). Thyroid follicular cell adenomas may have resulted from chronic stimulation of the thyroid gland by thyroid stimulating hormore (TISH) resulting from enhanced metab-	although the events reported occurred during treatment with SEROQUEL, they were not necessarily caused by it. Events are further categorized by body system and listed in order of decreasing frequency according to the following
psychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiologi- studies suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients	Information simulation of the trybuil gain by drybuil simulating information (157) resoluting from emailed olism and clearance of thyroxine by rodent liver. Changes in TSH, thyroxine, and thyroxine clearance consistent with this mechanism were observed in subchronic toxicity studies in rat and mouse and in a 1-year toxicity study in rat.	definitions: frequent adverse events are those occurring in at least 1/100 patients (only those not already listed in the tabulated results from placebo-controlled trials appear in this listing); infrequent adverse events are those occurring in
ted with the atypical antipsychotics. Precise risk estimates for hyperglycemia-related adverse events in patients ted with atypical antipsychotics are not available. Patients with an established diagnosis of diabetes mellitus who	uns mechanism were observed in subarrive toxicity sources in at an induce and on a "ryear lobality on in at, however, the results of these studies were not definitive. The relevance of the increases in thyroid follicular cell adei- nomas to human risk, through whatever mechanism, is unknown. Antipsychotic drugs have been shown to chroni-	1/100 to 1/1000 patients; rare events are those occurring in fewer than 1/1000 patients. Nervous System: Frequent: hypertonia, dysarthria; Infrequent: abnormal dreams, dyskinesia, thinking abnormal, tardive dyskinesia, vertigo, invol-
started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with factors for diabetes mellitus (eg, obesity, family history of diabetes) who are starting treatment with atypical	cally elevate protactin levels in rodents. Serum measurements in a 1-yo trobitly study showed that quetapine increased median serum protactin levels a maximum of 32- and 13-fold in male and female rats, respectively.	untary movements, confusion, amnesia, psychosis, hallucinations, hyperkinesia, libido increased*, urinary retention, incoordination, paranoid reaction, abnormal gait, myoclonus, delusions, manic reaction, apathy, ataxia, depersonal-
psychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during tment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia	Increases in mammary neoplasms have been found in rodents after chronic administration of other antipsychotic drugs and are considered to be prolactin-mediated. The relevance of this increased incidence of prolactin-mediated	ization, stupor, bruxism, catatonic reaction, hemiplegia; Rare : aphasia, buccoglossal syndrome, choreoathetosis, delir- ium, emotional lability, euphoria, libido decreased*, neuralgia, stuttering, subdural hematoma. Body as a Whole :
uding polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during tment with atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycemia	mammary gland tumors in rats to human risk is unknown (see Hyperprolactinemia in PRECAUTIONS , General). Mutagenesis: The mutagenic potential of quetiapine was tested in six <i>in vitro</i> bacterial gene mutation assays and in	Frequent: flu syndrome; Infrequent: neck pain, pelvic pain*, suicide attempt, malaise, photosensitivity reaction, chills, face edema, moniliasis; Rare: abdomen enlarged. Digestive System: Frequent: anorexia; Infrequent: increased sali
resolved when the atypical antipsychotic was discontinued; however, some patients required continuiation of anti- petic treatment despite discontinuation of the suspect drug. CAUTIONS: General: Orthostatic Hypotension: SEROUEL may induce orthostatic hypotension associated with	an in vitro mammalian gene mutation assay in Chinese Hamster Ovary cells. However, sufficiently high concentra- tions of quetiapine may not have been used for all tester strains. Quetapine did produce a reproducible increase in	vation, increased appetite, gamma glutamyl transpeptidase increased, gingivitis, dysphagia, flatulence, gastroenteritis, gastritis, hemorrhoids, stomatitis, thirst, tooth caries, fecal incontinence, gastroesophageal reflux, gum hemorrhage,
cerements, central of ministratic representation school of the manufacture of missian in proteins of a school with iness, tachycardia and, in some patients, syncope, especially during the initial dose-fittation period, probably ecting its α_radrenergic antagonist properties. Syncope was reported in 1% (23/2567) of the patients treated with	mutations in one Salmonella typhimurium tester strain in the presence of metabolic activation. No evidence of clas- togenic potential was obtained in an in vitro chromosomal aberration assay in cultured human lymphocytes or in the	mouth ulceration, rectal hemorrhage, tongue edema; Rare: glossitis, hematemesis, intestinal obstruction, melena, pancreatitis. Cardiovascular System: Frequent: palpitation; Infrequent: vasodilatation, QT interval prolonged,
NOUEL, compared with 0% (0/607) on placebo and about 0.4% (2/527) on active control drugs. SERQUEL Volue be used with particular caution in patients with known cardiovascular disease (history of myocardial infar-	in vivo micronucleus assay in rats. Impairment of Fertility: Quetiapine decreased mating and fertility in male Sprague-Dawley rats at oral doses of 50 and 150 mg/kg or 0.6 and 1.8 times the maximum human dose on a mg/m ²	migraine, bradycardia, cerebral ischemia, irregular pulse, T wave abnormality, bundle branch block, cerebrovascu- lar accident, deep thrombophlebitis, T wave inversion; Rare: angina pectoris, atrial fibrillation, AV block first degree,
or ischemic heart disease, heart failure or conduction abnormalities), cerebrovascular disease or conditions ch would predispose patients to hypotension (dehydration, hypovolemia and treatment with antihypertensive	basis. Drug-related effects included increases in interval to mate and in the number of matings required for success- ful impregnation. These effects continued to be observed at 150 mg/kg even after a two-week period without treat-	congestive heart failure, ST elevated, thrombophlebitis, T wave flattening, ST abnormality, increased QRS duration. Respiratory System: Frequent: pharyngitis, rhinitis, cough increased, dyspnea; Infrequent: pneumonia, epistaxis,
dications). The risk of orthostatic hypotension and syncope may be minimized by limiting the initial dose to mg bid. If hypotension occurs during titration to the target dose, a return to the previous dose in the titration	ment. The no-effect dose for impaired mating and fertility in male rats was 25 mg/kg, or 0.3 times the maximum human dose on a mg/m² basis. Quetiapline adversely affected mating and fertility in female Sprague-Dawley rats at an	asthma; Rare: hiccup, hyperventilation. Netabolic and Nutritional System: Frequent: peripheral edema; Infrequent: weight loss, alkaline phosphatase increased, hyperlipernia, alcohol intolerance, dehydration, hyperglycernia, creatinine
edule is appropriate. Cataracts: The development of cataracts was observed in association with quetiapine atment in chronic dog studies (see Animal Toxicology). Lens changes have also been observed in patients	oral dose of 50 mg/kg, or 0.6 times the maximum human dose on a mg/m² basis. Drug-related effects included decreases in matings and in matings resulting in pregnancy, and an increase in the interval to mate. An increase in the interval of the mating of	increased, hypoglycemia; Rare: glycosuria, gout, hand edema, hypokalemia, water intoxication. Skin and Appendages System: Frequent: sweating: Infrequent: pruritis, acne, eczema, contact dermatitis, maculopapular rash, seborrhea,
ing long-term SEROQUEL treatment, but a causal relationship to SÉROQUEL use has not been established. rertheless, the possibility of lenticular changes cannot be excluded at this time. Therefore, examination of	irregular estrus cycles was observed at doses of 10 and 50 mg/kg, or 0.1 and 0.6 times the maximum human dose on a mg/m ² basis. The no-effect dose in female rats was 1 mg/kg, or 0.01 times the maximum human dose on a mg/m ² basis. Pregnancy: Pregnancy Category C. The teratogenic potential of quetiaprice was studied in Wistar rats	skin ulcer; Rare: exfoliative dermatitis, psoriasis, skin discoloration. Urogenital System: Infrequent: dysmenorrhea*, vaginitis*, urinary incontinence, metrorrhagia*, impotence*, dysuria, vaginal moniliasis*, abnormal ejaculation*, cys-
lens by methods adequate to detect cataract formation, such as slit lamp exam or other appropriately sen- ve methods, is recommended at initiation of treatment or shortly thereafter, and at 6 month intervals during	Ingrim basis Freginairy - Freginairy - and guing the relation of the advecting of the detailer was solution in vision and and Dutch Belted rabbits dosed during the period of organogenesis. No evidence of a teratogenic effect was detected in rats at doses of 25 to 200 mg/kg or 0.3 to 2.4 times the maximum human dose on a mg/m ² basis or in rabbits at a solution.	titis, urinary frequency, amenorrhea*, female lactation*, leukorrhea*, vaginal hemorrhage*, vulvovaginitis* orchitis*; Rare: gynecomastia*, nocturia, polyuria, acute kidney failure. Special Senses: Infrequent: conjunctivitis, abnormal
onic treatment. Seizures: During clinical trials, seizures occurred in 0.6% (18/2792) of patients treated with ROQUEL compared to 0.2% (1/607) on placebo and 0.7% (4/527) on active control drugs. As with other antipsy-	25 to 100 mg/kg or 0.6 to 2.4 times the maximum human does on a mg/m basis. There was, however, evidence of embryo/fetal toxicity. Delays in skeletal ossification were detected in rat fetuses at doses of 50 and 200 mg/kg (0.6 and	vision, dry eyes, tinnitus, taste perversion, blepharitis, eye pain; Rare: abnormality of accommodation, deafness, glau- coma. Musculoskeletal System: Infrequent: pathological fracture, myasthenia, twitching, arthratgia, arthritis, leg
tics SEROQUEL should be used cautiously in patients with a history of seizures or with conditions that potentially or the seizure threshold, e.g., Alzheimer's dementia. Conditions that lower the seizure threshold may be more value to express the seizure threshold and the seiz	2.4 times the maximum human dose on a mg/m² basis) and in rabbits at 50 and 100 mg/kg (1.2 and 2.4 times the maximum human dose on a mg/m² basis). Fetal body weight was reduced in rat fetuses at 200 mg/kg and rabbit fetus-	cramps, bone pain. Hemic and Lymphatic System: Frequent: leukopenia; Infrequent: leukocytosis, anemia, ecchy- mosis, eosinophilia, hypochromic anemia; lymphadenopathy, cyanosis; Rare: hemolysis, thrombocytopenia.
valent in a population of 65 years or older. Hypothyroidism: Clinical trials with SEROQUEL demonstrated a dose- ted decrease in total and free thyroxine (T4) of approximately 20% at the higher end of the therapeutic dose range	es at 100 mg/kg (2.4 times the maximum human dose on a mg/m ² basis for both species). There was an increased incidence of a minor soft tissue anomaly (carpal/tarsal flexure) in rabbit fetuses at a dose of 100 mg/kg (2.4 times the	Endocrine System: Infrequent: hypothyroidism, diabetes mellitus; Rare: hyperthyroidism. *adjusted for gender. Post Marketing Experience: Adverse events reported since market introduction which were temporally related to SERO-
was maximal in the first two to four weeks of treatment and maintained without adaptation or progression dur- more chronic therapy. Generally, these changes were of no clinical significance and TSH was unchanged in most ents, and levels of TBG were unchanged. In nearly all cases, cessation of SEROOUEL treatment was associated	maximum human dose on a mg/m ² basis). Évidence of maternal toxicity (i.e., decreases in body weight gain and/or death) was observed at the high dose in the rat study and at all doses in the rabbit study. In a per/yostnatal repro-	ULL therapy include: leukopenia/neutropenia. If a patient develops a low white cell count consider discontinuation of therapy. Possible risk factors for leukopenia/neutropenia include pre-existing low white cell count and history of drug
enils, and reversion too where unchanged. In meanly an cases, cessation on Schoudel, treatment was associated a reversal of the effects on total and free T4, irrespective of the duration of treatment. About 0.4% (12/2791) SEROQUEL patients did experience TSH increases in monotherapy studies. Six of the patients with TSH increases	ductive study in rats, no drug-related effects were observed at doses of 1, 10, and 20 mg/kg or 0.01, 0.12, and 0.24 times the maximum human dose on a mg/m ² basis. However, in a preliminary peri/postnatal study, there were	induced leukopenia/neutropenia. Other adverse events reported since market introduction, which were temporally related to SERQUEL therapy, but not necessarily causally related, include the following: agranulocytosis, anaphylax-
endouce patients on experience rs-minicreases in minioralizity studies. Six of the patients with rs-minicreas- needed replacement thyroid treatment. In the mania adjunct studies, where SEROUEL was added to lithium or shorate, 12% (24/196) of SEROQUEL treated patients compared to 7% (15/203) of placebo treated patients had	increases in fetal and pup death, and decreases in mean litter weight at 150 mg/kg, or 3.0 times the maximum human dose on a mg/m ² basis. There are no adequate and well-controlled studies in pregnant women and quetiapine should	is, hyponatremia, rhabdomyolysis, syndrome of inappropriate antidiuretic hormone secretion (SIADH), and Stevens Johnson Svndrome (SIS).
aproder, iz a ceri 990 in Schoolet, treated patients compared in A (12/203) of patient of eater patients had raded TSH levels. Of the SEROOLEL treated patients with elevated TSH levels, 3 had simultaneous low free T4 els. Cholesterol and Triglyceride Elevations: In schizophrenia trials, SEROQUEL treated patients had increases	be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Labor and Delivery: The effect of SEROQUEL on labor and delivery in humans is unknown. Nursing Mothers: SEROQUEL was excreted in milk	DRUG ABUSE AND DEPENDENCE: Controlled Substance Class: SEROOUEL is not a controlled substance. Physical and Psychologic dependence: SEROOUEL has not been systematically studied, in animals or humans, for its poten-
n baseline in cholesterol and triglyceride of 11% and 17%, respectively, compared to slight decreases for place- patients. These changes were only weakly related to the increases in weight observed in SEROQUEL treated	of treated animals during lactation. It is not known if SEROQUEL is excreted in human milk. It is recommended that women receiving SEROQUEL should not breast feed. Pediatric Use: The safety and effectiveness of SEROQUEL in	and "systemidic dependence. This is to be systemication with a minima or minimar, or in sport tial for abuse, tolerance or physical dependence. While the clinical trials did not reveal any tendency for any drug-seek- ing behavior, these observations were not systematic and it is not possible to predict on the basis of this limited expe-
ents. Hyperprolactinemia: Although an elevation of prolactin levels was not demonstrated in clinical trials with ROQUEL, increased prolactin levels were observed in rat studies with this compound, and were associated with	pediatric patients have not been established. Geriatric Use: Of the approximately 3400 patients in clinical studies with SEROQUEL, 7% (232) were 65 years of age or over. In general, there was no indication of any different tolerability of	rience the extent to which a CNS-active drug will be misused, diverted, and/or abused once marketed. Consequently,
increase in mammary gland neoplasia in rats (see Carcinogenesis). Tissue culture experiments indicate that roximately one-third of human breast cancers are prolactin dependent in vitro, a factor of potential importance if	SEROQUEL in the elderly compared to younger adults. Nevertheless, the presence of factors that might decrease phar- macokinetic clearance, increase the pharmacodynamic response to SEROQUEL, or cause poorer tolerance or orthosta-	patients should be evaluated carefully for a history of drug abuse, and such patients should be observed closely for signs of misuse or abuse of SEROQUEL, e.g., development of tolerance, increases in dose, drug-seeking behavior. DVERDINGACE: Human avanciances: Evanciance with SEROPOLIC (underaine functional in cardio candreane ware lime.
prescription of these drugs is contemplated in a patient with previously detected breast cancer. Although distur- ces such as galactorrhea, amenorrhea, gynecomastia, and impotence have been reported with prolactin-elevat-	sis, should lead to consideration of a lower starting dose, slower titration, and careful monitoring during the initial dos- ing period in the elderly. The mean plasma clearance of SEROQUEL was reduced by 30% to 50% in elderly patients when compared to younger existence.	OVERDOSAGE: Human experience: Experience with SEROOUEL (quetiapine fumarate) in acute overdosage was lim- ited in the clinical trial database (6 reports) with estimated doses ranging from 1200 mg to 9600 mg and no talai- tise In operat; reported sions and symptoms were those resulting from an expension of the drive's known obs-
compounds, the clinical significance of elevated serum prolactin levels is unknown for most patients. Neither clin- studies nor epidemiologic studies conducted to date have shown an association between chronic administration		ties. In general, reported signs and symptoms were those resulting from an exaggeration of the drug's known phar- macological effects, i.e., drowsiness and sedation, tachycardia and hypotension. One case, involving an estimated particles of QROM may use associated with hypotension control theore hand those. In pact-marking experiments
his class of drugs and tumorigenesis in humans; the available evidence is considered too limited to be conclusive his time. Transaminase Elevations: Asymptomatic, transient and reversible elevations in serum transaminases with MT the hear energiest of the descent section of the section with the mean intermediate the section of the	over 3000 patients. This database includes 405 patients exposed to SEROQUEL for the treatment of acute bipolar mania (monotherapy and adjunct therapy) and approximately 2600 patients and/or normal subjects exposed to 1 or more doese of SEROVIEI for the treatment of exchangement of these anormately 3000 explored anormale and anormal subjects approximately and exchange of the second se	overdose of 9600 mg, was associated with hypokalemia and first degree heart block. In post-marketing experience, there have been very rare reports of overdose of SEROQUEL alone resulting in death, coma or OTc profougation. Management of Querdesace in case of service underspace schebils and marketing a pinzy and decum adjecute adjust of the compared of the service of the servi
marily ALT) have been reported. In schizophrenia trials, the proportions of patients with transaminase elevations 3 times the upper limits of the normal reference range in a pool of 3- to 6-week placebo-controlled trials were with the SCENDOUT commend to 10 for placement and the scheme the start the scheme trials the transmission of the scheme trials were scheme to 10 for the scheme trials were the scheme trials were the scheme trials were the scheme trials were the scheme trials were trials were triangle to 10 for the scheme trials were trials wer	more doses of SEROQUEL for the treatment of schizophrenia. Of these approximately 3000 subjects, approximately 2700 (2300 in schizophrenia and 406 in acute bipolar mania) were patients who partic-ipated in multiple dose effec- tiveness trials and their experience econsecond to approximately 4143 activatives. Pafer that full Describing	Management of Overdosage: In case of acute overdosage, establish and maintain an airway and ensure adequate oxygenation and vertilitation. Gastric lavage (after intubation, if patient is unconscious) and administration of activat- adaptement lawate units a bandwate according to the parameters of the bandwate according to the parameters of the paramete
roximately 6% for SEROQUEL compared to 1% for placebo. In acute bipolar mania trials, the proportions of ents with transaminase elevations of > 3 times the upper limits of the normal reference range in a pool of 3- to used elevation cartelled trials user approximativity 1% for betty ECEPOLIEL.	tiveness trials, and their experience corresponded to approximately 914.3 patient-years. Refer to the full Prescribing Information for details of adverse event data collection. Adverse Findings Observed in Short-Term, Controlled Trials: Adverse Vennt Associated with Discontinuation of Treatment in Short-Term, Placebo-Controlled Trials:	ed charcoal together with a laxative should be considered. The possibility of obtundation, seizure or dystonic reac- tion of the head and neck following overdose may create a risk of aspiration with induced emesis. Cardiovascular
week placebo-controlled trials were approximately 1% for both SEROQUEL and placebo. These hepatic enzyme rations usually occurred within the first 3 weeks of drug treatment and promptly returned to pre-study levels with rations treatment with SEROQUE. Behaviol and Constitution and Market International Second and American and American American and American Am American American	trais: Anverse Events Associated with Juscontinuation of treatment in Short-term, Placebo-controlled trais: Bipolar Mania: Overall, discontinuations due to adverse events were 5.7% for SEROQUEL vs. 5.1% for placebo in monotherapy and 3.6% for SEROQUEL vs. 5.9% for placebo in adjunct therapy. Schizophrenia: Overall, there was	monitoring should commence immediately and should include continuous electrocardiographic monitoring to detect possible arrhythmias. If antiarrhythmic therapy is administered, disopyramide, proclamamide and quinidine carry a
loing treatment with SEROUUEL Potential for Cognitive and Motor Impairment: Somnolence was a commonly orted adverse event reported in patients treated with SEROUUEL especially during the 3-5 day period of initial 	Infinitional day and 3.5% for SENGUGELVS. 3.3% for placedo in adjunct inergity. Sometymental. Overain, mine was little difference in the incidence of discontinuation due to adverse events (4% for SEROULE vs. 3% for placebo) in a pool of controlled trials. However, discontinuations due to somnolence and hypotension were considered to be drug	theoretical hazard of additive QT-prolonging effects when administered in patients with acute overdosage of SEROQUEL Similarly it is reasonable to expect that the alpha-adrenergic-blocking properties of bretelying might be
e-titration. In schizophrenia trials, somnolence was reported in 18% of patients on SEROQUEL compared to 11% Jacobo patients. In acute bipolar mania trials using SEROQUEL as monotherapy, somnolence was reported in 6.4 ordenter on SEROQUEL extension of a placeho acute La cavité biologra main trials using SEROQUEL (series SERO	a pool of controlled trais, however, discontinuations due to sommolence and hypotension were considered to de dug related (see PRECAUTIONS): Sommolence 0.8% vs 0% for placebo and Hypotension 0.4% vs 0% for placebo. Adverse Events Occurring at an Incidence of 1% or More Among SEROULEL Treated Patients in Short-Term.	additive to those of quetiapine, resulting in problematic hypotension. There is no specific antidote to SEROQUEL. Therefore appropriate supportive measures should be instituted. The possibility of multiple drug involvement should
6 of patients on SEROQUEL compared to 4% of placebo patients. In acute bipolar mania trials using SEROQUEL diguted therapy, somnolence was reported in 34% of patients on SEROQUEL compared to 9% of placebo patients. res SEROQUEL has the optient to impair judgment thinking or matter citile capitate should be cautioned about the second	Adverse Events Uccurning at an incluence of 1% of more Among SchulucL instead Patients in Shori Ierm, Placebo-Controlled Trials: The prescriber should be aware that the figures in the tables and tabulations in the full Prescribing Information cannot be used to predict the incidence of side effects in the course of usual medical prac-	be considered. Hypotension and circulatory collapse should be treated with appropriate measures such as intra- venous fluids and/or sympathomimetic agents (epinephrine and dopamine should not be used, since beta stimula-
ce SEROQUEL has the potential to impair judgment, thinking, or motor skills, patients should be cautioned about forming activities requiring mental alertness, such as operating a motor vehicle (including automobiles) or oper- g hazardous machinery unit lithey are reasonably certain that SEROUEL therapy does not affect them adverse-	Presching minimation cannot be used to predict the incluence of side energies in the course of usean mecuan plac- tice where patient characteristics and other factors differ from those that prevailed in the clinical trials. Similarly, the clieft frequencies cannot be compared with figures obtained from other clinical investigations involving different treat-	tion may worsen hypotension in the setting of quetiapine-induced alpha blockade). In cases of severe extrapyrami- dal symptoms, anticholinergic medication should be administered. Close medical supervision and monitoring should
g razarous machinery unu mey are reasonably certain that SENQUOLL interapy does not affect them adverse *riapism: One case of priapism in a patient receiving SEROQUEL has been reported prior to market introduction. lie a causal relationship to use of SEROQUEL has not been established, other drugs with alpha-adrenergic block-	Cited inequericites cannot be compared with ingues obtained non-order to mind investigations involving other in dar- ments, uses, and investigators. The cited figures, however, do provide the prescribing physician with some basis for estimating the relative contribution of drug and nondrug factors to the side effect incidence in the population studied.	continue until the patient recovers. SEROQUEL is a registered trademark of the AstraZeneca group of companies.
the a calcular relationship to use to conclude: has not been established, other origs with appreciation block- effects have been reported to induce pringing, and it is possible that SEROQUEL may share this capacity. Severe pism may require surgical intervention. Body Temperature Regulation: Although not reported with SEROQUEL,	Table 1, in the full Prescribing Information, enumerates the incidence, rounded to the nearest percent, of treatment- emergent adverse events that occurred during acute therapy of schizophrenia (up to 6 weeks) and bipolar mania (up	© AstraZeneca 2004, 2005 30198-00 Rev. 12/05 AstraZeneca Pharmaceuticals LP
	to 12 weeks) in 1% or more of patients treated with SEROQUEL (doses ranging from 75 to 800 mg/day) where the	

ications and simplify drug routines," Dr. Bogunovic said. Make sure to discuss the rationale for medications with staff and provide some information about possible drug-drug interactions.

Consulting psychiatrists should also arrange for brief psychiatric hospitalization when necessary. Psychiatrists are often called upon to make competency assessments.

Consulting psychiatrists also have an important role to play in helping nursing homes conform to requirements of the Omnibus Budget Reconciliation Act (OBRA). These regulations require that individuals admitted for the first time to a nursing home be prescreened for major psychiatric disorders.

In addition, every 3 months, nursing homes are required to complete a mini-

	r
	mum data set.
Between 91% and	This tool ad-
94% of nursing	dresses patient
	mood, cogni-
home residents	tion, communi-
have some type of	cation and be-
	havioral
psychiatric	patterns, psy-
disorder. But only	chosocial well-
-	being, comor-
2.3% of residents	bid conditions,
receive	and medica-
psychiatric	tions.
psychiatric	The OBRA
consultations.	regulations also
	require clear

documentation of the need for psychotropic medication use.

Once a patient is prescribed psychotropic medication, psychiatrists should attempt to reduce the dosage at regular intervals.

"The requirement is that nursing home residents should be maintained on minimal effective dosages," Dr. Bogunovic said.

Sometimes nursing home residents must be hospitalized in a psychiatric ward, especially if they are assaultive or suicidal. "But the patient should be initially screened, because a lot of medical conditions may present with psychiatric symptoms," Dr. Bogunovic said.

Psychiatrists can be instrumental in arranging the acceptance of temporarily nospitalized patients back into the nursng home.

Educating nursing home staff is one of the key roles for a psychiatrist. Nursing home staff are often poorly trained, and turnover rates are high. "I personally have experienced that these staff were really not aware and were not educated about psychiatric symptoms of dementia," Dr. Bogunovic said.

Psychiatrists should consider giving inservice training on signs and symptoms of psychiatric disorders, stages of dementia, drug-drug interactions, pharmacologic and nonpharmacologic management, infury prevention, and minimizing restraint use, he suggested.

It might also be worthwhile to train staff in the administration of assessment tools, such as the Mini Mental State Examination or the Global Deterioration Scale, Dr. Bogunovic said.