Front

Qutyl XR®
[Quetiapine Fumarate]

کیوٹِل ایکس آر

COMPOSITION:
Qutyl XR Tablet 150 mg:
Each extended release film coated tablet contains:
Quetiapine Fumarate equivalent to
Quetiapine ..... 150 mg.

Product Specs.: USP

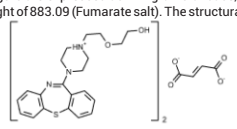
Qutyl XR Tablet 200 mg:
Each extended release film coated tablet contains:
Quetiapine Fumarate equivalent to
Quetiapine ..... 200 mg.

Product Specs.: USP

Qutyl XR Tablet 300 mg:
Each extended release film coated tablet contains:
Quetiapine Fumarate equivalent to
Quetiapine ..... 300 mg.

Product Specs.: USP

DESCRIPTION:
Qutyl XR (quetiapine fumarate) is a psychotropic agent belonging to a chemical class, the dibenzothiazepine derivatives. The chemical designation is 2-[2-(4-dibenzo [b,f] [1,4]thiazepin-11-yl-1piperazinyl)ethoxy]-ethanol fumarate (2:1) (salt). It is present in tablets as the fumarate salt. All doses and tablet strengths are expressed as milligrams of base, not as fumarate salt. Its molecular formula is $C_{42}H_{50}N_6O_4S.C_4H_4O_4$ and it has a molecular weight of 883.09 (Fumarate salt). The structural formula is:



CLINICAL PHARMACOLOGY:
The mechanism of action of Qutyl XR, as with other drugs having efficacy in the treatment of schizophrenia, bipolar disorder and major depressive disorder (MDD), is unknown. However, it has been proposed that the efficacy in schizophrenia is mediated through a combination of dopamine type 2 (D2) and serotonin type 2A (5HT2A) antagonism. The active metabolite, N-desalkyl quetiapine (norquetiapine), has similar activity at D2, but greater activity at 5HT2A receptors, than the parent drug (quetiapine). Quetiapine's efficacy in bipolar depression and MDD may partly be explained by the high affinity and potent inhibitory effects that norquetiapine exhibits for the norepinephrine transporter. Antagonism at receptors other than dopamine and serotonin with similar or greater affinities may explain some of the other effects of quetiapine and norquetiapine: Antagonism at histamine H1 receptors may explain the somnolence, antagonism at adrenergic α1b receptors may explain the orthostatic hypotension, and antagonism at muscarinic M1 receptors may explain the anticholinergic effects.
Pharmacodynamics:
Quetiapine and norquetiapine have affinity for multiple neurotransmitter receptors including dopamine D1 and D2, serotonin 5HT1A and 5HT2A, histamine H1, muscarinic M1, and adrenergic α1b and α2 receptors. Quetiapine differs from norquetiapine in having no appreciable affinity for muscarinic M1 receptors whereas norquetiapine has high affinity. Quetiapine and norquetiapine lack appreciable affinity for benzodiazepine receptors.
Pharmacokinetics:
Following multiple dosing of quetiapine up to a total daily dose of 800 mg, administered in divided doses, the plasma concentration of quetiapine and norquetiapine, the major active metabolite of quetiapine, were proportional to the total daily dose. Accumulation is predictable upon multiple dosing. Steady-state mean C_{max} and AUC of norquetiapine are about 21-27% and 46-56%, respectively of that observed for quetiapine. Elimination of quetiapine is mainly via hepatic metabolism. The mean-terminal half-life is approximately 7 hours for quetiapine and approximately 12 hours for norquetiapine within the clinical dose range. Steady-state concentrations are expected to be achieved within two days of dosing. Qutyl XR is unlikely to interfere with the metabolism of drugs metabolized by cytochrome P450 enzymes.
Absorption: Quetiapine fumarate reaches peak plasma concentrations approximately 6 hours following administration. Qutyl XR dosed once daily at steady-state has comparable bioavailability to an equivalent total daily dose of Qutyl XR administered in divided doses, twice daily. A high-fat meal (approximately 800 to 1000 calories) was found to produce statistically significant increase in C_{max} and AUC of 44% to 52% and 20% to 22%, respectively, for the 50 mg and 300 mg tablets. In comparison, a light meal (approximately 300 calories) had no significant effect on the C_{max} or AUC of quetiapine. It is recommended that Qutyl XR be taken without food or with a light meal.
Distribution: Quetiapine is widely distributed throughout the body with an apparent volume of distribution of 10±4 L/kg. It is 83% bound to plasma proteins at therapeutic concentrations. In vitro, quetiapine did not affect the binding of warfarin or diazepam to human serum albumin. In turn, neither warfarin nor diazepam altered the binding of quetiapine.
Metabolism and Elimination: Following a single oral dose of 14C-quetiapine, less than 1% of the administered dose was excreted as unchanged drug, indicating that quetiapine is highly metabolized. Approximately 73% and 20% of the dose was recovered in the urine and feces, respectively. The average dose fraction of free quetiapine and its major active metabolite is <5% excreted in the urine. Quetiapine is extensively metabolized by the liver. The major metabolic pathways are sulfoxidation to the sulfoxide metabolite and oxidation to the parent acid metabolite; both metabolites are pharmacologically inactive. In vitro studies using human liver microsomes revealed that the cytochrome P450 3A4 isoenzyme is involved in the metabolism of quetiapine to its major, but inactive, sulfoxide metabolite and in the metabolism of its active metabolite norquetiapine.
Age: Oral clearance of quetiapine was reduced by 40% in elderly patients (> 65 years, n = 9) compared to young patients (n = 12), and dosage adjustment may be necessary.
Gender: There is no gender effect on the pharmacokinetics of quetiapine.
Race: There is no race effect on the pharmacokinetics of quetiapine.
Smoking: Smoking has no effect on the oral clearance of quetiapine.
Renal Insufficiency: Patients with severe renal impairment (CLcr=10-30 mL/min/1.73m^2, n=8) had a 25% lower mean oral clearance than normal subjects (CLcr>80 mL/min/1.73m^2, n=8), but plasma quetiapine concentrations in the subjects with renal insufficiency were within the range of concentrations. Dosage adjustment is therefore not needed in these patients.
Hepatic Insufficiency: Hepatically impaired patients (n=8) had a 30% lower mean oral clearance of quetiapine than normal subjects. In 2 of the 8 hepatically impaired patients, AUC and C_{max} were 3 times higher than those observed typically in healthy subjects. Since quetiapine is extensively metabolized by the liver, higher plasma levels are expected in the hepatically impaired population, and dosage adjustment may be needed.

DRUG-DRUG INTERACTIONS:
In vitro enzyme inhibition data suggest that quetiapine and of its metabolites would have little inhibitory effect on in vivo metabolism mediated by cytochromes P450 1A2, 2C9, 2C19, 2D6 and 3A4.

INDICATIONS AND USAGE:
Schizophrenia: Qutyl XR is indicated for the treatment of schizophrenia. The efficacy in schizophrenia was established in one 6 week and one maintenance trial in adults with schizophrenia as well by extrapolation from three 6-week trials in adults with schizophrenia treated with Qutyl XR.
Bipolar Disorder. Qutyl XR is indicated for the acute treatment of manic or mixed episodes associated with bipolar I disorder, both as monotherapy and as an adjunct to lithium or divalproex. Qutyl XR is indicated for the acute treatment of depressive episodes associated with bipolar disorder. The efficacy of Qutyl XR was established in one 8-week trial in adults with bipolar I or II disorder as well as extrapolation from two 8-week trials in adults with bipolar I or II disorder treated with Qutyl XR. Qutyl XR is indicated for the maintenance treatment of bipolar I disorder, as an adjunct to lithium or divalproex. Efficacy was extrapolated from two maintenance trials in adults with bipolar I disorder treated. The effectiveness of monotherapy for the maintenance treatment of bipolar disorder has not been systematically evaluated in controlled clinical trials.
Adjunctive Treatment of Major Depressive Disorder (MDD): Qutyl XR is indicated for use as adjunctive therapy to antidepressants for the treatment of MDD. The efficacy as adjunctive therapy to antidepressants in MDD was established in two 6-week trials in adults with MDD who had an inadequate response to antidepressant treatment.

DOSAGE AND ADMINISTRATION:
Qutyl XR tablets should be swallowed whole and not split, chewed or crushed. It is recommended that tablet should be taken without food or with a light meal (approximately 300 calories).
Schizophrenia:
Dose Selection: Qutyl XR should be administered once daily, preferably in the evening. The recommended initial dose is 300 mg/day. Patients should be titrated within a dose range of 400 mg/day – 800 mg/day depending on the response and tolerance of the individual patient. Dose increases can be made at intervals as short as 1 day and in increments of up to 300 mg/day. The safety of doses above 800 mg/day has not been evaluated in clinical trials.
Maintenance Treatment: A maintenance trial in adult patients with schizophrenia treated with Qutyl XR has shown this drug to be effective in delaying time to relapse in patients who were stabilized on Qutyl XR at doses of 400 mg/day to 800 mg/day for 16 weeks. Patients should be periodically reassessed to determine the need for maintenance treatment and the appropriate dose for such treatment.
Bipolar Disorder: Bipolar mania usual dose for acute monotherapy or adjunct therapy (with lithium or divalproex).
Dose Selection: When used as monotherapy or adjunct therapy (with lithium or divalproex), Qutyl XR should be administered once daily in the evening starting with 300 mg on Day 1 and 600 mg on Day 2. Qutyl XR can be adjusted between 400 mg and 800 mg beginning on Day 3 depending on the response and tolerance of the individual patient.
Recommended Dosing Schedule:
- Day 1: Qutyl XR 300 mg
- Day 2 : Qutyl XR 600 mg
- Day 3 : Qutyl XR 400 mg to 800 mg

Depressive Episodes Associated with Bipolar Disorder.
Usual Dose: Should be administered once daily in the evening to reach 300 mg/day by Day 4.
Recommended Dosing Schedule:
- Day 1 : 50 mg
- Day 2 : 100 mg
- Day 3 : 200 mg
- Day 4 : 300 mg

Maintenance Treatment for Bipolar I Disorder.
Maintenance of efficacy in bipolar I disorder was demonstrated with Qutyl XR (administered twice daily totaling 400 mg/day to 800 mg/day) as adjunct therapy to lithium or divalproex. Generally, in the maintenance phase, patients continued on the same dose on which they were stabilized during the stabilization phase. Patients should be periodically reassessed to determine the need for maintenance treatment and the appropriate dose for such treatment.
Major Depressive Disorder, Adjunctive Therapy with Antidepressants:
Dose Selection: Qutyl XR in a dose range of 150 mg/day to 300 mg/day was demonstrated to be effective as adjunctive therapy to antidepressants. Begin with 50 mg once daily in the evening. On Day 3, the dose can be increased to 150 mg once daily in the evening. There were dose-dependent increases in adverse reactions in the recommended dose range of 150 mg/day to 300 mg/day. Doses above 300 mg/day were not studied.

DOSING IN SPECIAL POPULATIONS:
Consideration should be given to a slower rate of dose titration and a lower target dose in the elderly and in patients who are debilitated or who have a predisposition to hypotensive reactions. When indicated, dose escalation should be performed with caution in these patients. Elderly patients should be started on Qutyl XR 50 mg/day and the dose can be increased in increments of 50 mg/day depending on the response and tolerance of the individual patient. Patients with hepatic impairment should be started on Qutyl XR 50 mg/day. The dose can be increased daily in increments of 50 mg/day to an effective dose, depending on the clinical response and tolerance of the patient. The elimination of quetiapine was enhanced in the presence of phenytoin. Higher maintenance doses of quetiapine may be required when it is co-administered with phenytoin and other enzyme inducers such as carbamazepine and phenobarbital.
Re-initiation of Treatment in Patients Previously Discontinued: Although there are no data to specifically address re initiation of treatment, it is recommended that when restarting therapy of patients who have been off Qutyl XR for more than one week, the initial dosing schedule should be followed. When restarting patients who have been off Qutyl XR for less than one week, gradual dose escalation may not be required and the maintenance dose may be reinitiated.
Switching Patients to QUTYL XR Tablets: Patients who are currently being treated with immediate release formulation may be switched to Qutyl XR at the equivalent total daily dose taken once daily. Individual dosage adjustments may be necessary.
Switching from Antipsychotics: There are no systematically collected data to specifically address switching patients from other antipsychotics to Qutyl XR, or concerning concomitant administration with other antipsychotics. While immediate discontinuation of the previous antipsychotic treatment may be acceptable for some patients, more gradual discontinuation may be most appropriate for others. In all cases, the period of overlapping antipsychotic administration should be minimized. When switching patients from depot antipsychotics, if medically appropriate, initiate Qutyl XR therapy in place of the next scheduled injection. The need for continuing existing extrapyramidal syndrome medication should be re-evaluated periodically.

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CONTRAINDICATIONS: None

WARNINGS AND PRECAUTIONS:
Increased Mortality in Elderly Patients with Dementia Related Psychos Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death compared to placebo. Qutyl XR (quetiapine fumarate) is not approved for the treatment of patients with dementia-related psychosis.
Clinical Worsening and Suicide Risk: Patients with major depressive disorder (MDD), both adult and pediatric, may experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality) or unusual changes in behavior, whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs. Suicide is a known risk of depression and certain other psychiatric disorders, and these disorders themselves are the strongest predictors of suicide. There has been a long-standing concern, however, that antidepressants may have a role in inducing worsening of depression and the emergence of suicidality in certain patients during the early phases of treatment.
All patients being treated with antidepressants for any indication should be monitored appropriately and observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases: The following symptoms, anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia (psychomotor restlessness), hypomania, and mania, have been reported in adult and pediatric patients being treated with antidepressants for major depressive disorder as well as for other indications, both psychiatric and non psychiatric. Although a causal link between the emergence of such symptoms and either the worsening of depression and/or the emergence of suicidal impulses has not been established, there is concern that such symptoms may represent precursors to emerging suicidality. Consideration should be given to changing the therapeutic regimen, including possibly discontinuing the medication, in patients whose depression is persistently worse, or who are experiencing emergent suicidality or symptoms that might be precursors to worsening depression or suicidality, especially if these symptoms are severe, abrupt in onset, or were not part of the patient's presenting symptoms. Families and caregivers of patients being treated with antidepressants for major depressive disorder or other indications, both psychiatric and nonpsychiatric, should be alerted about the need to monitor patients for the emergence of agitation, irritability, unusual changes in behavior, and the other symptoms described above, as well as the emergence of suicidality, and to report such symptoms immediately to healthcare providers. Such monitoring should include daily observation by families and caregivers.
Neuroleptic 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, including quetiapine. Rare cases of NMS have been reported with quetiapine. Clinical manifestations of NMS are hyperpyrexia, muscle rigidity, altered mental status, and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis) and acute renal failure. The diagnostic evaluation of patients with this syndrome is complicated. In arriving at a diagnosis, it is important to exclude cases where the clinical presentation includes both serious medical illness (eg, pneumonia, systemic infection, etc.) and untreated or inadequately treated extrapyramidal signs and symptoms (EPS). Other important considerations in the differential diagnosis include central anticholinergic toxicity, heat stroke, drug fever and primary central nervous system (CNS) pathology.
The management of NMS should include: Immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy; intensive symptomatic treatment and medical monitoring; and treatment of any concomitant serious medical problems for which specific treatments are available. There is no general agreement about specific pharmacological treatment regimens for NMS. If a patient requires antipsychotic drug treatment after recovery from NMS, the potential reintroduction of drug therapy should be carefully considered. The patient should be carefully monitored since recurrences of NMS have been reported.
Hyperglycemia: In some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics, including quetiapine. Epidemiological studies suggest an increased risk of treatment-emergent hyperglycemia-related adverse reactions in patients treated with the atypical antipsychotics. Precise risk estimates for hyperglycemia-related adverse reactions in patients treated with atypical antipsychotics are not available.

DRUG INTERACTIONS:
The risks of using Qutyl XR in combination with other drugs have not been extensively evaluated in systematic studies. Given the primary CNS effects of Qutyl XR, caution should be used when it is taken in combination with other centrally acting drugs. Because of its potential for inducing hypotension, Qutyl XR may enhance the effects of certain antihypertensive agents. Qutyl XR may antagonize the effects of levodopa and dopamine agonists.
The Effect of Other Drugs on Quetiapine:
Phenytoin: Co-administration of quetiapine (250 mg three times/day) and phenytoin (100 mg three times/day) increased the mean oral clearance of quetiapine by 5-fold. Increased doses of Qutyl XR may be required to maintain control of symptoms of schizophrenia in patients receiving quetiapine and phenytoin, or other hepatic enzyme inducers (eg, carbamazepine, barbiturates, rifampin, glucocorticoids). Caution should be taken if phenytoin is withdrawn and replaced with a noninducer (eg, valproate).
Divalproex: Co-administration of quetiapine (150 mg bid) and divalproex (500 mg twice daily) increased the mean maximum plasma concentration of quetiapine at steady-state by 17% without affecting the extent of absorption or mean oral clearance.
Thioridazine: Thioridazine (200 mg twice daily) increased the oral clearance of quetiapine (300 mg twice daily) by 65%.
Cimetidine: Administration of multiple daily doses of cimetidine (400 mg three times daily for 4 days) resulted in a 20% decrease in the mean oral clearance of quetiapine (150 mg three times daily). Dosage adjustment for quetiapine is not required when it is given with cimetidine.
P450 3A Inhibitors: Co-administration of ketoconazole (200 mg once daily for 4 days), a potent inhibitor of cytochrome P450 3A, reduced oral clearance of quetiapine by 84%, resulting in a 335% increase in maximum plasma concentration of quetiapine. Caution (reduced dosage) is indicated when Qutyl XR is administered with ketoconazole and other inhibitors of cytochrome P450 3A (eg, itraconazole, fluconazole, erythromycin, protease inhibitors).
Fluoxetine, Imipramine, Haloperidol, and Risperidone: Co-administration of fluoxetine (60 mg once daily), imipramine (75 mg twice daily), haloperidol (7.5 mg twice daily), or risperidone (3 mg twice daily) with quetiapine (300 mg twice daily) did not alter the steady-state pharmacokinetics 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 three times daily dosing.
Divalproex: The 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 twice daily) was administered with quetiapine (150 mg twice daily). The mean oral clearance of total valproic acid (administered as divalproex 500 mg twice daily) was increased by 11% in the presence of quetiapine (150 mg twice daily). The changes were not significant.
Lithium Concomitant: Administration of quetiapine (250 mg three times daily) 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 three times daily schedule) of quetiapine to subjects with selected 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 cytochrome P450 mediated metabolism of antipyrine.

WARNING & PRECAUTIONS:
Increased Mortality in Elderly Patients with Dementia-Related Psychos:
Antipsychotic drugs, including quetiapine, are associated with an increased risk of death; causes of death are variable.
Suicidality and Antidepressant Drugs: Increased the risk of suicidal thinking and behavior in children, adolescents and young adults taking antidepressants for major depressive disorder and other psychiatric disorders.
Neuroleptic Malignant Syndrome (NMS): Manage with immediate discontinuation and close monitoring.
Hyperglycemia and Diabetes Mellitus (DM): Ketoacidosis, hyperosmolar coma and death have been reported in patients treated with atypical antipsychotics, including quetiapine. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. When starting treatment, patients with diabetes or risk factors for diabetes should undergo blood glucose testing before and during treatment.
Hyperlipidemia: Undesirable alterations in lipids have been observed. Increases in total cholesterol, LDL-cholesterol and triglycerides and decreases in HDL-cholesterol have been reported in clinical trials. Appropriate clinical monitoring is recommended, including fasting blood lipid testing at the beginning of, and periodically, during treatment.
Weight Gain: Patients should receive regular monitoring of weight.
Tardive Dyskinesia: Discontinue if clinically appropriate.
Orthostatic Hypotension: Associated dizziness, tachycardia and syncope may occur especially during the initial dose titration period. Use in caution in patients with known cardiovascular or cerebrovascular disease.
Increased Blood Pressure in Children and Adolescents: Blood pressure should be measured at the beginning of, and periodically during treatment in children and adolescents.
Qutyl XR has not been evaluated in pediatric patients: Leukopenia, Neutropenia and Agranulocytosis: have been reported with atypical antipsychotics including Qutyl XR. Patients with a pre-existing low white cell count (WBC) or a history of leukopenia/neutropenia should have complete blood count (CBC) monitored frequently during the first few months of treatment and should discontinue at the first sign of a decline in WBC in absence of other causative factors.
Cataracts: Lens changes have been observed in patients during long-term quetiapine treatment. Lens examination is recommended when starting treatment and at 6-month intervals during chronic treatment.
Suicide: The possibility of a suicide attempt is inherent in schizophrenia and bipolar disorder, and close supervision of high risk patients should accompany drug therapy.

USE IN SPECIFIC POPULATION:
Pregnancy:
Category C: There are no adequate and well-controlled studies of Qutyl XR use in pregnant women. In limited published literature, there were no major malformations associated with quetiapine exposure during pregnancy. In animal studies, embryo-fetal toxicity occurred. Quetiapine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. There are limited published data on the use of quetiapine for treatment of schizophrenia and other psychiatric disorders during pregnancy.
Labor and Delivery: The effects o on labor and delivery are unknown.
Nursing Mothers:
Qutyl XR was excreted into human milk. Caution should be exercised when Qutyl XR is administered to a nursing woman.
Pediatric Use Safety and Effectiveness: Qutyl XR have not been established in pediatric patients and is not approved for patients under the age of 18 years.
Geriatric Use: Sixty-eight patients in clinical studies with Qutyl XR were 65 years of age or over. In general, there was no indication of any different tolerability of Qutyl XR in the elderly compared to younger adults. Nevertheless, the presence of factors that might decrease pharmacokinetic clearance, increase the pharmacodynamic response, or cause poorer tolerance or orthostasis, should lead to consideration of a lower starting dose, slower titration, and careful monitoring during the initial dosing period in the elderly.
Renal Impairment: Clinical experience with Qutyl XR in patients with renal impairment is limited.
Hepatic Impairment: Since quetiapine is extensively metabolized by the liver, higher plasma levels are expected in the hepatically impaired population, and dosage.

ADVERSE REACTIONS:
Most common adverse reactions (incidence ≥5% and twice placebo) in decreasing frequency are: somnolence, dry mouth, constipation, dizziness, increased appetite, dyspepsia, weight gain, fatigue, dysarthria, and nasal congestion.
Post Marketing Adverse reactions:
Other adverse reactions reported since market introduction, which were temporally related to therapy, but not necessarily causally related, include the following: agranulocytosis, cardiomyopathy hyponatremia, myocarditis rhabdomyolysis, syndrome of inappropriate antidiuretic hormone secretion (SIADH), Stevens-Johnson syndrome (SJS), and decreased platelets. In post-marketing clinical trials, elevations in total cholesterol (predominantly LDL cholesterol) have been reported.

OVERDOSAGE:
In case of acute over dosage, establish and maintain an airway and ensure adequate oxygenation and ventilation. Gastric lavage (after intubation, if patient is unconscious) and administration of activated charcoal together with a laxative should be considered. The possibility of obtundation, seizure or dystonic reaction of the head and neck following overdose may create a risk of aspiration with induced emesis. Cardiovascular monitoring should commence immediately and should include continuous electrocardiographic monitoring to detect possible arrhythmias. If antiarrhythmic therapy is administered, disopyramide, procainamide and quinidine carry a theoretical hazard of additive prolonging effects when administered in patients with acute overdosage. Similarly, it is reasonable to expect that the αadrenergic-blocking properties of bretylium might be additive to those of quetiapine, resulting in problematic hypotension. There is no specific antidote. Therefore, appropriate supportive measures should be instituted.

INSTRUCTIONS:
Store below 30ºC. Protect from heat, sunlight & moisture. Keep out of the reach of children. To be sold on the prescription of a registered medical practitioner only.

PRESENTATION:

Qutyl XR Tablet 150 mg	:	Pack of 1 x 10 tablets.
Qutyl XR Tablet 200 mg	:	Pack of 1 x 10 tablets.
Qutyl XR Tablet 300 mg	:	Pack of 1 x 10 tablets.

ہدایات:
۳۰ درجہ سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
گرمی، دھوپ اور نمی سے بچائیں۔
بچوں کی پہنچ سے دور رکھیں۔
صرف ڈاکٹر کے نسخہ پر فروخت کریں۔

FOR FURTHER INFORMATION PLEASE CONTACT:

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