laxative should be considered. Cardiovascular monitoring should commence immediately and should include continuous electrocardiographic monitoring to detect possible arrhythmias.

HOW SUPPLIED

Revoc film coated tablets are available in the following strengths:
Revoc Tablets **1 mg** in blister of 1x10's pack.
Revoc Tablets **2 mg** in blister of 1x10's pack.
Revoc Tablets **3 mg** in blister of 1x6's pack.
Revoc Tablets **4 mg** in blister of 1x10's pack.
Revoc Oral Solution 1mg/ml is available in 60 ml bottle.

STORAGE CONDITIONS

Store below 30°C in a dry place, protect from light.
To be dispensed on the prescription of a registered medical practitioner only.
Keep out of the reach of children.

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر خشک جگہ پر رکھیں،
روشنی سے بچائیں۔ صرف رجسٹرڈ ڈاکٹر کے نسخے پر فروخت کریں۔
بچوں کی پہنچ سے دور رکھیں۔

Note: Tablets contain lactose. **نوٹ:** ٹیبلیٹس میں لیکٹوز شامل ہے۔

Manufactured by:
Platinum Pharmaceuticals (Pvt) Ltd.
A-20, North Western Industrial Zone,
Bin Qasim, Karachi-75020, Pakistan.

Mfg. Lic No. 000415 QAR No. AW21-0812-02

Revoc
(Risperidone)

Available in
1 mg, 2 mg, 3 mg, 4 mg Tablets
& 1mg/ml Oral Solution

COMPOSITION

Revoc Tablets 1 mg
Each film coated tablet contains
Risperidone .....1 mg.
Product Complies U.S.P. Specs.

Revoc Tablets 2 mg
Each film coated tablet contains
Risperidone ..... 2 mg.
Product Complies U.S.P. Specs.

Revoc Tablets 3 mg
Each film coated tablet contains
Risperidone .....3 mg.
Product Complies U.S.P. Specs.

Revoc Tablets 4 mg
Each film coated tablet contains
Risperidone .....4 mg.
Product Complies U.S.P. Specs.

Revoc Oral Solution
Each ml contains:
Risperidone 1mg
Product Complies U.S.P. Specs.

DESCRIPTION

Revoc (Risperidone) is a novel antipsychotic belonging to a new class of antipsychotic agents, the benezisoxazole-derivatives.

PROPERTIES

Pharmacodynamics: Risperidone is a selective monoaminergic antagonist with unique properties. It has a high affinity for serotoninergic 5-HT_2 and dopaminergic D_2 receptors. Risperidone binds also to alpha$_1$ adrenergic receptors, and, with lower affinity, to H_1-histaminergic and alpha$_2$ -adrenergic receptors. Risperidone has no affinity for cholinergic receptors. Although Risperidone is a potent D_2 antagonist, which is considered to improve the positive symptoms of schizophrenia, it causes less depression of motor activity and induction of catalepsy than classical neuroleptics. Balanced central serotonin and dopamine antagonism may reduce extrapyramidal side effect liability and extend the therapeutic activity to the negative and affective symptoms of schizophrenia.

Pharmacokinetics: Risperidone is completely absorbed after oral administration, reaching peak plasma concentration within 1 to 2 hours. The absorption is not affected by food and thus Risperidone can be given with or without meals.

Risperidone is metabolized by cytochrome P-450 IID6 to 9-hydroxy-risperidone which has a similar pharmacological activity as risperidone. Risperidone plus 9-hydroxy-risperidone form the active antipsychotic fraction. Another metabolic pathway of risperidone is N-dealkylation.

Risperidone is rapidly distributed. The volume of distribution is 1-2 L / kg. In plasma, Risperidone is bound to albumin and alpha1-acid glycoprotein. The plasma protein binding of Risperidone is 88%, that of 9-hydroxy-risperidoneis 77%.

INDICATIONS
Revoc is indicated for the treatment of acute and chronic schizophrenic psychoses, and other psychotic conditions, in which positive symptoms (such as hallucinations, delusions, thought disturbances, hostility, suspiciousness) and/or negative symptoms (such as blunted affect, emotional and social withdrawal, poverty of speech) are prominent. Revoc also alleviates affective symptoms (such as depression, guilt feelings, anxiety) associated with schizophrenia.

Revoc is also indicated as long-term therapy for the prevention of relapse (acute exacerbations) in chronic schizophrenic patients.

In addition, Revoc is indicated for the treatment of behavioral disturbances in patients with dementia in whom symptoms such as aggressiveness (verbal outbursts, physical violence), activity disturbances (agitation, wandering) or psychotic symptoms are prominent.

CONTRAINDICATION
Risperidone is contraindicated in patients with a known hypersensitivity to the product.

WARNING AND CONTRAINDICTIONS
Due to the alpha-blocking activity of Revoc (orthostatic) hypotension can occur, especially during the initial dose-titration period. Revoc should be used with caution in patients with known cardiovascular disease (e.g. heart failure, myocardial infarction, conduction abnormalities, dehydration, hypovolaemia, or cerebrovascular disease), and the dosage should be gradually titrated as recommended (see Dosage and Administration). A dose reduction should be considered if hypotension occurs.

It is recommended to halve both the starting dose and the subsequent dose increments in geriatric patients and in patients with renal or liver insufficiency. Caution is also due when prescribing Revoc to patients with Parkinson's disease since, theoretically, it might cause a deterioration of the disease. Classical neurolepitcs are known to lower the seizure threshold. Caution is recommended when treating patients with epilepsy. Patients may be advised to refrain from excessive eating in view of the possibility of weight gain.

Interactions: Revoc should be used with caution in combination with other centrally acting drugs. Revoc may antagonize the effect of levodopa and other dopamine-agonists. Carbamazepine has been shown to decrease the plasma levels of the active antipsychotic fraction of Revoc. Similar effects may be observed with other hepatic enzyme inducers. On discontinuation of carbamazepine or other hepatic enzyme inducers the dosage of Revoc should be re-evaluated and if necessary decreased. Phenothiazines, tricyclic antidepressants and some beta-blockers may increase the plasma concentrations of Risperidone but not those of the antipsychotic fraction. When Revoc is taken together with other highly protein-bound drugs, there is no clinically relevant displacement of either drug from the plasma proteins.

Pregnancy and Lactation: The safety of Risperidone for use during human pregnancy has not been established. Although, in experimental animals, Risperidone did not show direct reproductive toxicity, some indirect, prolactin and CNS-mediated effects were observed. No teratogenic effect of Risperidone was noted in any study. Therefore, Revoc should only be used during pregnancy if the benefits outweigh the risks.

It is not known whether Revoc is excreted in human milk. In animal studies, Risperidone and 9-hydroxy-risperidone are excreted in the milk. Therefore, women receiving Revoc should not breast feed.

Effects on Driving Ability and Use of Machinery: Revoc may interfere with activities requiring mental alertness. Therefore, patients should be advised not to drive or operate machinery until their individual susceptibility is known.

DOSAGE AND ADMINISTRATION
Switching from other antipsychotics
When medically appropriate, gradual discontinuation of the previous treatment while Revoc therapy is initiated is recommended. Also if medically appropriate, when switching patients from depot antipsychotics, initiated Revoc therapy in place of the next scheduled injection. The need for continuing existing anti-parkinson medications should be re-evaluated periodically.

Adults: Patients should be titrated to 3 mg b.i.d. gradually over three days. All patients, whether acute or chronic, should start with 1 mg Risperidone b.i.d. The dosage should be increased to 2 mg b.i.d. on the second day and 3 mg b.i.d. on the third day. From then on the dosage can be maintained unchanged, or further individualized, if needed. The usual optimal dosage is 2 to 4 mg b.i.d.

Elderly: A starting dose of 0.5 mg b.i.d. is recommended. This dosage can be individually adjusted with 0.5 mg b.i.d. increments to 1 to 2 mg b.i.d.

Children: Experience is lacking in children aged less than 15 years.

Renal and liver disease: A starting dose of 0.5 mg b.i.d. is recommended. This dosage can be individually adjusted with 0.5 mg b.i.d. increments to 1 to 2 mg b.i.d.

ADVERSE REACTIONS
Revoc is generally well tolerated and in many instances it has been difficult to differentiate adverse events from symptoms of the underlying disease. Adverse events observed in association with the use of Risperidone are Insomnia, Agitation, Anxiety, Headache. Less Common: Somnolence, fatigue, dizziness, impaired concentration, constipation, dyspepsia, nausea / vomiting, abdominal pain, blurred vision, priapism, erectile dysfunction, ejaculatory dysfunction, orgastic dysfunction, urinary incontinence, rhinitis, rash and other allergic reactions.

OVERDOSAGE
Symptoms: In general, reported signs and symptoms have been those resulting from an exaggeration of the drug's known pharmacological effects. These include drowsiness and sedation, tachycardia and hypotension, and extrapyramidal symptoms.

Treatment: Establish and maintain a clear airway and ensure adequate oxygenation and ventilation. Gastric lavage (after intubation, if the patient is unconscious) and administration of activated charcoal together with a