

1.6 Product Information

1.6.3 Patient Information Leaflet (PIL)

Mockup for package insert of RISDONE-2 (Risperidone Tablets USP 2 mg) is enclosed in subsequent pages.

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only.

RISDONE

(Risperidone Tablets USP 1, 2, 3, & 4 mg)

PRESCRIBING INFORMATION:

Risdone (Risperidone) is an antipsychotic agent which belongs to the group of benzisoxazole derivatives. It is indicated in the treatment of psychotic disorders.

COMPOSITION

RISDONE 1

Each uncoated tablet contains:
Risperidone USP 1 mg

RISDONE 2

Each uncoated tablet contains:
Risperidone USP 2 mg

RISDONE 3

Each uncoated tablet contains:
Risperidone USP 3 mg

RISDONE 4

Each uncoated tablet contains:
Risperidone USP 4 mg

Clinical Pharmacology

Risdone is a selective monoaminergic antagonist with a high affinity for both serotonergic 5-HT₂ and dopaminergic D₂ receptors. Risdone produces its antipsychotic activity through a combination of dopamine type 2(D₂) and serotonin type 2 (5HT₂) antagonism. Risdone is completely absorbed after oral administration, reaching peak plasma concentration within 1 to 2 hours. The absorption is not affected by food. It is metabolized in the liver to 9-hydroxyrisperidone which has a similar pharmacological activity to Risdone. After oral administration, the elimination half-life of the active antipsychotic fraction is 24 hours. The absolute bioavailability of Risdone is 70%. It is 70% to 90% plasma protein bound.

Indications:

Risdone is indicated for the treatment of acute and chronic schizophrenic psychoses and other psychotic conditions in which positive symptoms and/or negative symptoms are prominent. Risdone also alleviates affective symptoms associated with schizophrenia.

Dosage and administration:

Risdone is administered on a twice daily schedule, generally beginning with 1 mg twice daily initially. It is increased in increments of 1 mg twice daily on the second and third day, as tolerated. The usual optional dosage is 2 to 4 mg twice daily. Further dosage adjustment if indicated should generally be made at intervals of not less than one week. In elderly patients and patients with hepatic & renal

disease starting dose of Risdone 0.5 mg is given twice a day. Dosage can be individually adjusted with 0.5 mg twice a day.

Contraindications, precautions & Warnings:

It is contraindicated in patients with known hypersensitivity to benzisoxazole derivatives. Caution should be exercised in patients with cardiovascular diseases, parkinson's disease, epilepsy, etc. If signs and symptoms of tardive dyskinesia appear, therapy should be discontinued.

Use in pregnancy and lactation:

Use in pregnancy, lactation & children is not recommended.

Drug Interactions:

Risdone antagonizes the effects of levodopa and other dopamine agonists. It also interacts with phenothiazines, tricyclic antidepressants, beta blockers and the plasma concentration of Risdone may be increased but not of the antipsychotic fraction.

Side effects:

Risdone is generally well tolerated. It causes insomnia, somnolence, fatigue, dizziness, constipation, dyspepsia, nausea, abdominal pain, blurred vision, erectile dysfunction, etc. The incidence and severity of extrapyramidal symptoms are less.

Overdosage:

The symptoms of overdosage are drowsiness, sedation, tachycardia, hypotension and extrapyramidal symptoms. There is no specific antidote to Risdone. Treatment of overdosage is symptomatic and through supportive measures.

Storage

Store below 30°C, protected from light and moisture.

Presentation

Risdone 1, 2, 3 and 4 mg tablets are available in blister strips of 10's

Manufactured by :

INTAS

INTAS PHARMACEUTICALS LTD.

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