

Riscord

Risperidone BP

Presentation

Riscord 1 Tablet: Each tablet contains Risperidone BP 1 mg

Riscord 2 Tablet: Each tablet contains Risperidone BP 2 mg

Riscord 4 Tablet: Each tablet contains Risperidone BP 4 mg

Pharmacodynamic Properties

Risperidone is a selective monoaminergic antagonist having a high affinity for serotonergic 5-HT₂ and dopaminergic D₂ receptors. Risperidone binds also to alpha₁ adrenergic receptors and with lower affinity to histamine H₁ and alpha₂ adrenergic receptors. Risperidone has no affinity for cholinergic receptors. Risperidone, as a potent D₂ antagonist, improves the positive symptoms of schizophrenia but causes less depression of motor activity. 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.

Pharmacokinetic Properties

Absorption

Risperidone is completely absorbed after oral administration, reaching peak plasma concentrations within 1 to 2 hours. The absolute oral bioavailability of Risperidone is 70%. The absorption is not affected by food and thus Risperidone can be given with or without meals. Steady-state of Risperidone is reached within 1 day in most patients.

Distribution

Risperidone is rapidly distributed. The volume of distribution is 1-2 mg /kg. In plasma, Risperidone is bound to albumin and alpha1-acid glycoprotein. The plasma protein binding of Risperidone is 90%.

Biotransformation and elimination

Risperidone is metabolised by CYP2D6 to 9-Hydroxy-Risperidone, which has a similar pharmacological activity as Risperidone. Extensive CYP2D6 metabolisers convert Risperidone rapidly into 9-Hydroxy-Risperidone, whereas poor CYP2D6 metabolisers convert it much more slowly. Another metabolic pathway of Risperidone is N-dealkylation. In vitro studies in human liver microsomes showed that Risperidone at clinically relevant concentration does not substantially inhibit the metabolism of medicines metabolised by cytochrome P₄₅₀ isozymes. One week after administration, 70% of the dose is excreted in the urine and 14% in the faeces. After oral administration to psychotic patients, Risperidone is eliminated with a half-life of about 3 hours.

Linearity

Risperidone plasma concentrations are dose-proportional within the therapeutic dose-range.

Indications

- For the treatment of acute and chronic schizophrenia
- For the short term treatment of acute manic and mixed episodes associated with Bipolar I Disorder.
- For the treatment of irritability associated with autistic disorder.

Dosage & Administration

Risperidone may be given in 1 or 2 divided doses daily. The usual initial daily dose of Risperidone is 2 mg on the first day, 4 mg on the second day, and 6 mg on the third day. Further dosage adjustment may be needed and should generally be made at intervals of not less than one week; usual maintenance dose is 4 to 6 mg daily

Elderly

An initial dose of 0.5 mg twice daily slowly increased in steps of 0.5 mg twice daily of 1 to 2 mg twice daily is suggested for the elderly and for patients with renal or hepatic impairment. Safety and effectiveness in children have not been established.

Contraindications

Hypersensitivity to Risperidone.

Precautions

Risperidone should be used with caution in patients with hepatic or renal impairment and parkinson's disease, pregnancy, breast feeding.

Drug Interactions

Risperidone may interfere with elimination by the kidneys of clozapine, a different type of anti-psychotic medication, causing increased levels of clozapine in the blood. This could increase the risk of side effects with clozapine. Antacids containing aluminium or magnesium should not be taken one hour before taking this drug and never right after.

Side Effects

Side effects that have been most frequently reported with Risperidone include nausea, headache, insomnia, dry mouth, dizziness, constipation, sweating, nervousness, asthenia. Orthostatic hypotension has been seen occasionally. Other side effects reported include anorexia, dyspepsia, abdominal pain, anxiety, sexual dysfunction, visual disturbances, vasodilatation, vomiting, tremor, abdominal dreams chills, palpitations, agitation, rashes, convulsion, and hypertension.

Use in Pregnancy and Lactation

Risperidone should be used in pregnancy only if the potential benefits outweigh the potential risk to the fetus and it is recommended that women receiving Risperidone should not breast – feed.

Commercial Pack

Riscord 1 Tablet: Each box contains 5 Alu- Alu blister packs of 10 tablets.

Riscord 2 Tablet: Each box contains 3 Alu- Alu blister packs of 10 tablets.

Riscord 4 Tablet: Each box contains 3 Alu- Alu blister packs of 10 tablets.

Manufactured by: