

Risponex

Risperidone USP

Composition:

Risponex 2 Tablet: Each tablet contains Risperidone USP 2 mg.

Risponex 4 Tablet: Each tablet contains Risperidone USP 4 mg.

Pharmacology: Risperidone is a benzisoxazole derivative, it is an antipsychotic agent. Risperidone's antipsychotic activity is attributed to its antagonist activity at both dopamine (D2 subtype) and serotonin (5HT2 subtype) receptors. Risperidone is also an antagonist of alpha 1, alpha 2 and H1 receptor subtypes which mediate non- antipsychotic effects of the drug.

Indications: Risponex (Risperidone) is indicated for the management of manifestations of psychotic disorders.

- Acute schizophrenia
- Chronic schizophrenia
- Affective symptomatology of schizophrenia
- Treatment of irritability associated with autistic disorder
- Other psychoses

Dosage and administration: Children: Bipolar mania: <10 yrs: not established. ≥10 yrs: Initially 0.5 mg once daily (AM or PM), may adjust at intervals of at least 24 hrs by 0.5 mg–1mg/day to target doses of 1–2.5 mg/day. Usual range: 1–6 mg/day, max 6mg/day. **If somnolence occurs:** give ½ daily dose twice daily. **Irritability with autism:** <5 yrs: not recommended. ≥ 5 years of age: weight <20 kg: initially 0.25 mg/day, may increase to 0.5 mg/day after ≥4 days. Weight ≥20 kg: initially 0.5mg/day, may increase to 1mg/day after ≥4 days. Usual range: 0.5–3 mg/day. <15 kg: use cautiously.

Adult: Initially 2–3 mg once daily, may adjust at intervals of at least 24hrs by 1 mg/day. Usual range: 1–6 mg/day, max 6 mg/day. Elderly, debilitated, hypotensive, severe renal or hepatic impairment: 0.5 mg twice daily, adjust in increments of up to 0.5mg twice daily, titrate at intervals of at least 1 week if exceeding 1.5 mg twice daily, may switch to once-daily dosing after titration.

Contraindication: Hypersensitivity to risperidone.

Warnings and Precautions: Elderly patients with dementia treated with atypical antipsychotic drugs had an increased mortality rate. Dehydration was an overall risk factor for mortality and should therefore Risperidone be carefully avoided in elderly patients with dementia. Risperidone is not recommended for the treatment of behavioral symptoms of dementia because of an increased risk of cerebrovascular adverse events (including cerebrovascular accidents and transient ischaemic attacks). Due to the alpha-blocking activity of Risperidone, orthostatic hypotension can occur, especially during the initial dose-titration period. A dose reduction should be considered if hypotension occurs. Drugs with dopamine receptor antagonistic properties have been associated with the induction of tardive dyskinesia. If signs and symptoms of tardive dyskinesia appear, the discontinuation of all antipsychotic drugs should be considered. Neuroleptic malignant syndrome characterized by hyperthermia, muscle rigidity, autonomic instability, altered consciousness and elevated CPK levels has been reported to occur with neuroleptics. In this event all antipsychotic drugs including Risperidone should be discontinued. Caution should also be exercised when prescribing Risperidone to patients with Parkinson's disease since, theoretically, it may cause a deterioration of the disease. Caution is recommended when treating patients with epilepsy. Use of Risperidone for schizophrenia in children aged less than 15 years has not been formally evaluated.

Side effects: Extrapyramidal symptoms (exclusively in doses above 6 mg/day), tremor, rigidity, hypokinesia, dystonia, dizziness, constipation, anxiety, somnolence, rash, rhinitis, tachycardia. Arthralgia, aggressive reaction, visual disturbances are rarely happen

Use in Pregnancy and Lactation: There are no adequate and well-controlled studies. Therefore, risperidone should be used only if the potential benefit justifies the potential risk to the fetus.

Use in Children & adolescents: Risponex is indicated for the treatment of acute manic or mixed episodes associated with Bipolar I Disorder in children and adolescents.

Drug interactions: Given the primary CNS effects of Risperidone, it should be used with caution in combination with other centrally acting drugs including alcohol. On initiation of Carbamazepine or other hepatic enzyme-inducing drugs, the dosage of Risperidone should be re-evaluated and increased if necessary. Conversely, on discontinuation of such drugs, the dosage of Risperidone should be re-evaluated and decreased if necessary. When concomitant Fluoxetine or Paroxetine is initiated or discontinued, the physician should re-evaluate the dosing of Risperidone. Risperidone does not show a clinically relevant effect on the pharmacokinetics of Valproate or Topiramate. Food does not affect the absorption of Risperidone from the stomach.

Overdose: Drowsiness, sedation, tachycardia, hypotension and extrapyramidal symptoms may occur. In case of severe extrapyramidal symptoms, anticholinergic medication should be administered. Close medical supervision and monitoring should continue until the patient recovers. There is no specific antidote to Risperidone.

Storage

Store in a cool (below 30 °C) and dry place, protect from light. Keep all medicines out of the reach of children.

How Supplied:

Risponex 2 Tablet: Each box contains 3X10's tablets in Alu-Alu blister pack.

Risponex 4 Tablet: Each box contains 3X10's tablets in Alu-Alu blister pack.



Manufactured by:
Goodman Pharmaceuticals Ltd.
Better Health For All
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