

Risomax[®]

Risperidone

Description

Risomax[®] is the preparation of Risperidone which is an atypical antipsychotic. It is a selective monoaminergic antagonist possessing a high affinity for serotonergic 5-HT₂ & dopaminergic D₂ receptors. It also binds to adrenergic receptors and with lower affinity to H₁ histamine receptors & alpha-2 adrenergic receptors. Being a potent D₂ antagonist, it improves positive symptoms of schizophrenia, but causes less pyramidal side effects liability and extends the therapeutic activity to the negative and affective symptoms of schizophrenia.

Indications and Uses

Risomax[®] is indicated for the treatment of-

- Acute and chronic schizophrenia
- Bipolar mania (as mono therapy or as adjunctive therapy)
- Irritability associated with autistic disorder

Dosage & administration

Schizophrenia

Adults (18 years & above): Initial dose is 2 mg and may be increased in increments of 1 to 2 mg per day at interval of 24 hours or more, as tolerated, may be administered orally once a day or in divided doses twice a day. Doses above 12 mg per day were not demonstrated to be more efficacious and were associated with more extrapyramidal symptoms and other adverse effects.

Adolescents (12 to 17 years): Initial dose 0.5 mg and may be increased in increments of 0.5 mg to 1 mg per day at interval of 24 hours or more, as tolerated, may be administered orally once a day or in divided doses twice a day; patients experiencing somnolence may be benefitted from twice a day dosing.

Bipolar Mania

Adults (18 years & above): Initial dose is 2 mg and may be increased in increments of 1 mg per day at interval of 24 hours or more, as tolerated, may be administered orally once a day or in divided doses twice a day; patients experiencing somnolence may benefit from twice a day dosing.

Adolescents (10 years to 17 years): Initial dose is 0.5 mg may be increased in increments of 0.5 mg to 1 mg per day at interval of 24 hours or more, as tolerated. It may be administered orally once a day or in divided doses twice a day; patients experiencing somnolence may benefit from twice a day dosing. It is used as mono therapy or as adjunctive therapy with lithium or valproate for the treatment of acute manic or mixed episodes associated with bipolar mania.

Irritability associated with autistic disorder

Children and Adolescents

Aged 5 to 17 years having weight greater than 15 but less than 20 kg: Initial dose is 0.25 mg and after a minimum of 4 days, may be increased to 0.5 mg per day; maintain this dose for a minimum of 14 days; subsequent dose increases may be made in increments of 0.25 mg at intervals of 2 weeks or more, as tolerated. Recommended dose: 0.5 mg orally per day.

Aged 5 to 17 years having weight more than 20 kg: Initial dose is 0.5 mg, after a minimum of 4 days, may be increased to 1 mg per day; maintain this dose for a minimum of 14 days; subsequent dose increases in increments of 0.5 mg at intervals of 2 weeks or more, as tolerated. Recommended dose: 1 mg orally per day.

Recommended daily dosage by indications

	Initial Dose	Target Dose	Effective Dose Range
Schizophrenia: adults	2 mg	4 to 8 mg	4 to 16 mg
Schizophrenia: adolescents	0.5 mg	3 mg	1 to 6 mg
Bipolar mania: adults	2 to 3 mg	1 to 6 mg	1 to 6 mg
Bipolar mania: children and adolescents	0.5 mg	1 to 2.5 mg	1 to 6 mg
Irritability associated with autistic disorder: children and adolescents	0.25 mg (Weight < 20 kg) 0.5 mg (Weight ≥ 20 kg)	0.5 mg (<20 kg) 1 mg (≥20 kg)	0.5 to 3 mg

Use in Special Populations

Patients with renal or hepatic impairment: Use a lower starting dose of 0.5 mg twice daily, may increase to dosages above 1.5 mg twice daily at intervals of at least one week.

Pregnancy & lactation

Pregnancy category C. Risperidone should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Risperidone may be excreted in breast milk. Therefore, women receiving Risperidone should not breast-feed, use only if potential benefit outweighs risks.

Side effects

Common side effects include headache, dizziness, drowsiness, tired feeling, tremors, twitching or uncontrollable muscle movements, agitation, anxiety, restless feeling, depressed mood, dry mouth, upset stomach, constipation, weight gain and pain in arms or legs etc.

Less common side effects are absent, missed or irregular menstrual periods, body aches or pain, breast swelling or soreness, chills, darkening of skin color, decreased interest in sexual intercourse, dry skin, ear congestion, fever, increased watering of the mouth and joint pain etc.

Precautions

Special precaution should be taken in case of preexisting cardiovascular diseases, discontinue use if signs and symptoms of tardive dyskinesia occur, renal & hepatic impairment, elderly epilepsy, Parkinson's disease and in pregnancy.

Drug interaction

Risperidone may interfere with elimination by the kidneys of clozapine, a different type of antipsychotic 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.

Overdose

In general, reported signs and symptoms are those resulting from an exaggeration of the drug's known pharmacological effects, i.e., drowsiness and sedation, tachycardia & hypotension, and extrapyramidal symptoms. Acute Risperidone overdose estimates doses of up to 360 mg. In case of overdose, provide supportive care including close medical supervision and monitoring. There is no specific antidote to Risperidone. Treatment should consist of general measures employed in the management of overdose with any drug. Ensure an adequate airway, oxygenation, and ventilation. Monitor cardiac rhythm and vital signs. Use supportive and symptomatic measures.

Contraindications

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

Pharmaceutical precautions

Store in a cool (below 25°C) & dry place. Protect from light. Keep out of the reach of children.

Presentation

Risomax[®] 1 tablet: Each coated tablet contains Risperidone BP 1 mg.

Risomax[®] 2 tablet: Each coated tablet contains Risperidone BP 2 mg.

Risomax[®] 4 tablet: Each coated tablet contains Risperidone BP 4 mg.

Package quantities

Risomax[®] 1 tablet: Carton of 50 tablets in blister pack.

Risomax[®] 2 tablet: Carton of 50 tablets in blister pack.

Risomax[®] 4 tablet: Carton of 50 tablets in blister pack.

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ACI Limited
Godhnyl, Narayanganj, Bangladesh