Abridged Prescribing Information:

Active Ingredient: RISDONE tablet contains Risperidone 1mg / 2mg / 3 mg / 4mg. RISDONE MT contains melt-in-mouth (orally disintegrating, dissolving in mouth) Risperidone 0.5 mg / 1mg / 2mg in tablet form.

Indication: Treatment of schizophrenia in adults and adolescents aged 13-17 years, Alone, or in combination with lithium or valproate, for the short-term treatment of acute manic or mixed episodes associated with bipolar I disorder in adults, and alone in children and adolescents aged 10-17 years, Treatment of irritability associated with autistic disorder in children and adolescents aged 5-16 years. **Dosage & Administration**: **For schizophrenia**: Initial dose – 0.5-2mg/day, target dose – 3-8 mg /day. **For Bipolar mania**: Initial dose – 0.5-2 mg/day, target dose – 1-6 mg /day. **Irritability associated with autistic disorder in children/ adolescents -** Initial dose – 0.25 mg/day, target dose – 0.5 - 1 mg /day. **Co-Administration of RISDONE with Certain Other Medications:** Enzyme inducers (viz., carbamazepine phenytoin, rifampin, phenobarbital) may reduce the efficacy of RISDONE treatment. Concurrent use of RISDONE with these drugs necessitates appropriate RISDONE dosage titration especially during initiation or discontinuation of therapy with these inducers. **Administration of RISDONE MT:** RISDONE MT tablets should be taken out of the blister pack just before administration and then promptly placed on the tongue. The MT tablets disintegrate in the mouth within seconds and can be swallowed subsequently with or without liquid. Once removed from the blister unit, these tablets cannot be stored. **Contraindication:** Hypersensitivity to risperidone, or to any component of the products. **Warnings & Precautions: Increased Mortality in Elderly Patients with Dementia-Related Psychosis:** Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. RISDONE (risperidone) is not approved for the treatment of dementia-related psychosis. **Cerebrovascular Adverse Events, Including Stroke, in Elderly Patients with Dementia:** Cerebrovascular adverse events (e.g., stroke, transient ischemic attack), including fatalities, were reported in elderly patients (mean age 85 years; range 73-97) with dementia-related psychosis. Risperidone is not approved for the treatment of patients with dementia-related psychosis. **Neuroleptic Malignant Syndrome (NMS):** This is a rare but potentially fatal condition reported to occur with antipsychotic drugs. Clinical manifestations are hyperpyrexia, muscle rigidity, altered mental status, and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). Additional signs may include elevated creatinine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. **Tardive Dyskinesia:** This is a syndrome of potentially irreversible, involuntary, dyskinetic movements that may develop in patients treated with antipsychotic drugs over a prolonged period. **Suicide:** Because of the possibility of suicide attempt being inherent in patients with schizophrenia and bipolar mania, prescriptions for RISDONE should be written for the smallest quantity of tablets, consistent with good patient management, in order to reduce the risk of overdose. **Pregnancy:** Pregnancy Category C. RISDONE should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. **Specific Population:** The recommended initial dose is 0.5 mg twice daily in patients who are elderly or debilitated, patients with severe renal or hepatic impairment, and patients either predisposed to hypotension or for whom hypotension would pose a risk. Dosage increases in these patients should be in increments of no more than 0.5 mg twice daily. Increases to dosages above 1.5 mg twice daily should generally occur at intervals of at least 1 week. In some patients, slower titration may be medically appropriate. **Geriatric Use:** Risk of orthostatic hypotension in the elderly may be minimized by limiting the initial dose to 0.5 mg twice daily followed by careful titration. Monitoring of orthostatic vital signs should be considered. Also, it may be useful to monitor renal function. **Adverse Reactions:** The most common adverse reactions in clinical trials (≥10%) were somnolence, appetite increased, fatigue, rhinitis, upper respiratory tract infection, vomiting, coughing, urinary incontinence, saliva increased, constipation, fever, Parkinsonism, dystonia, abdominal pain, anxiety, nausea, dizziness, dry mouth, tremor, rash, akathisia, and dyspepsia. The majority of all adverse reactions were mild to moderate in severity. **Overdose:** Acute risperidone overdosage (20 to 360 mg) has been associated with drowsiness, sedation, tachycardia, hypotension, and extrapyramidal symptoms but no fatalities. Prolonged QT interval, widened QRS, hyponatremia, hypokalemia, and convulsions are other adverse reactions reported. Torsade de pointes has been reported in association with combined overdose of risperidone and paroxetine. In case of acute overdosage, establish and maintain an airway and ensure adequate oxygenation and ventilation. Gastric lavage (after intubation, if patient is unconscious) and administration of activated charcoal together with a laxative should be considered. Because of the rapid disintegration of RISDONE MT mouth dissolving tablets, pill fragments may not appear in gastric contents obtained with lavage. There is no specific antidote to risperidone. Hypotension and circulatory collapse should be treated with appropriate measures, such as intravenous fluids and/or sympathomimetic agents (epinephrine and dopamine should not be used, since beta-adrenergic receptor stimulation may worsen hypotension in the setting of risperidone-induced alpha-adrenergic receptor blockade).

(For details, please refer full prescribing information)

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