

Modesto™

Paliperidone Tablet

Presentation

Modesto™ XR 3: Each extended release tablet contains Paliperidone USP 3 mg.

Modesto™ XR 6: Each extended release tablet contains Paliperidone USP 6 mg.

Description

Paliperidone is a psychotropic agent belonging to the chemical class of benzisoxazole derivatives. Paliperidone is the major active metabolite of Risperidone. It is a centrally active dopamine Type 2 (D₂) antagonist and with predominant serotonin Type 2 (5-HT_{2A}) antagonist activity. It is also active as an antagonist at α_1 and α_2 adrenergic receptors and H₁ histaminergic receptors, which may explain some of the other effects of the drug. It has no affinity for cholinergic muscarinic or β_1 - and β_2 -adrenergic receptors.

Indications and usage

Paliperidone is indicated for-

- Schizophrenia, including acute treatment and recurrence prevention
- Treatment of Schizoaffective disorder as monotherapy and in combination with antidepressants or mood stabilizers

Dosage and administration

- The recommended dose of Paliperidone-

| Indication | Initial dose | Recommended dose | Maximum dose |
|---------------------------------|--------------------|------------------|--------------|
| Schizophrenia-adults | 6 mg/day | 3-12 mg/day | 12 mg/day |
| Schizophrenia-adolescents | Weight < 51kg | 3 mg/day | 3-6 mg/day |
| | Weight \geq 51kg | 3 mg/day | 3-12 mg/day |
| Schizoaffective disorder-adults | 6 mg/day | 3-12 mg/day | 12 mg/day |

- Paliperidone can be taken with or without food. It must be swallowed whole with the aid of liquids. Tablets should not be chewed, divided or crushed.

Adverse reactions

The most common adverse reactions of Paliperidone are tachycardia, akathisia, somnolence, tremor, dystonia, cogwheel rigidity, anxiety, weight increased, dyspepsia, constipation, nasopharyngitis etc.

Contraindications

Paliperidone is contraindicated in patients with a known hypersensitivity to either Paliperidone or Risperidone or to any excipients in Paliperidone.

Precautions

Caution should be exercised when Paliperidone is prescribed in patients with known Cardiovascular diseases, QT prolongation, Neuroleptic malignant syndrome, Tardive dyskinesia, Hyperglycemia, Dyslipidemia, Obesity, Hyperprolactinemia, Leukopenia, Neutropenia, Agranulocytosis, Seizures, Potential for Cognitive & Motor impairment etc.

Drug interactions

- Paliperidone should be used with caution in combination with other centrally acting drugs and alcohol. It may antagonize the effect of Levodopa and other dopamine agonists.
- Because of its potential for inducing orthostatic hypotension, an additive effect may be observed when Paliperidone is administered with other therapeutic agents that have this potential.
- Strong CYP3A4/P-glycoprotein (P-gp) inducers: It may be necessary to increase the dose of Paliperidone when a strong inducer of both CYP3A4 and P-gp (e.g. Carbamazepine) is co-administered. Conversely, on discontinuation of the strong inducer, it may be necessary to decrease the dose of Paliperidone.
- Co-administration of Divalproex sodium increased C_{max} and AUC of Paliperidone by approximately 50%. Adjust dose of Paliperidone if necessary based on clinical assessment.

Use in pregnancy and lactation

Pregnancy: Pregnancy Category C. There are no adequate and well-controlled studies in pregnant women. Paliperidone should be used during pregnancy only if the potential benefits justifies the potential risk to the fetus.

Lactation: Paliperidone is excreted in human breast milk. The known benefits of breastfeeding should be weighed against the unknown risks of infant exposure to Paliperidone.

Pediatric use

Safety and effectiveness in the treatment of Schizophrenia not established in patients less than 12 years of age. Safety and effectiveness in the treatment of Schizoaffective disorder not established in patients less than 18 years of age.

Overdose

Overdose of Paliperidone is limited; there is no specific antidote to Paliperidone. If overdose occurs general supportive and symptomatic measures should be employed.

Storage

Do not store above 30° C. Keep away from light and out of the reach of children.

Commercial Pack

Modesto™ XR 3: Each bottle contains 15 tablets.

Modesto™ XR 6: Each bottle contains 15 tablets.