

Repitol[®]

Ropinirole
Tablet

Description

Ropinirole is a dopamine D₂ receptor agonist which improves the symptoms & signs in Parkinson's disease. It is believed to be due to stimulation of post synaptic dopamine D₂ type receptor within the caudate-putamen in the brain.

Indications

Ropinirole is used alone or with other medicines to treat Parkinson's disease. It helps to improve muscle control and movement difficulties. Thus, is also used to treat a condition called Restless Legs Syndrome (RLS). This condition is an overwhelming feeling of wanting to move the legs to make them comfortable from unpleasant sensations in the legs.

Dosage and Administration

In all clinical studies, dosage was initiated at a sub therapeutic level and gradually titrated to therapeutic response. The dosage should be increased to achieve a maximum therapeutic effect, balanced against the principal side effects of nausea, dizziness, somnolence and dyskinesia.

The recommended starting dose is 0.25 mg three times daily with or without food. Based on individual patient response, dosage should then be titrated with weekly increments as described in the table below. After week 4, if necessary, daily dosage may be increased by 1.5 mg per day on a weekly basis up to a dose of 9 mg per day, and then by up to 3 mg per day weekly to a total dose of 24 mg per day.

Ascending – Dose Schedule of Ropinirole

Week	Dosage	Total Daily Dose
1	0.25 mg three times daily	0.75 mg
2	0.5 mg three times daily	1.5 mg
3	0.75 mg three times daily	2.25 mg
4	1.0 mg three times daily	3.0 mg

Dosage greater than 24 mg/day have not been tested in clinical trials.

Ropinirole should be discontinued gradually over a 7 day period. The frequency of administration should be reduced from three times daily to twice daily for 4 days. For the remaining 3 days, the frequency should be reduced to once daily prior to complete withdrawal of Ropinirole.

Side Effects

Some of the side effects that are known to be associated with Ropinirole are abdominal pain, swelling of the legs and ankles due to excess fluid retention (peripheral oedema), confusion, difficulty performing voluntary movements, resulting in jerky or involuntary movements or muscle twitches (dyskinesia), false perceptions of things that are not really there (hallucinations), nausea and vomiting, sleepiness (somnolence), fainting (syncope), slower than normal heart beat (bradycardia), profound drop in blood pressure (hypotension).

Contraindications

Ropinirole is contraindicated for patients known to have hypersensitivity to the product.

Precautions

If a patient develops significant daytime sleepiness or episodes of falling asleep during activities that require active participation (e.g. conversations, eating, etc.), Ropinirole should ordinarily be discontinued. If a decision is made to continue Ropinirole, patients should be advised to no drive and to avoid other potentially dangerous activities.

Use in Pregnancy and Lactation

Pregnancy: Pregnancy category C. There are no adequate and well-controlled studies using Ropinirole in pregnant women. Ropinirole should be used during pregnancy only if the potential benefit outweighs the potential risk of the fetus.

Nursing Mothers: Ropinirole inhibits prolactin secretion in humans and could potentially inhibit lactation. Because of the potential for serious adverse reactions in nursing infants from Ropinirole, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use: Safety and effectiveness of Ropinirole in the pediatric population have not been established.

Drug Interactions

Co-administration of Ropinirole with carbidopa or L-dopa or digoxin or theophylline did not show any interaction between them to hamper pharmacological effect. Co-administration of ciprofloxacin (500 b.i.d.), an inhibitor of CYP_{1A2} (enzyme responsible for Ropinirole metabolism), with

Ropinirole (2 mg t.i.d.) increased Ropinirole AUC by 84%. Since ropinirole is a dopamine agonist, it is possible that dopamine antagonists, such as neuroleptics (phenothiazines, butyrophenones, thioxanthenes) or metoclopramide, may diminish the effectiveness of Ropinirole.

Pharmaceuticals Precautions

Store in a cool and dry place, away from light. Keep out of reach of children.

Commercial Pack

Repitol[®] 0.25 tablet: Box containing 30 tablets in 3 x 10's blister strips. Each tablet contains Ropinirole Hydrochloride INN equivalent to Ropinirole 0.25 mg.
Repitol[®] 2 tablet: Box containing 30 tablets in 3 x 10's blister strips. Each tablet contains Ropinirole Hydrochloride INN equivalent to Ropinirole 2 mg.



Manufactured by

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