Perkirol®

Ropinirole 0.25 mg

Composition: Perkirol® 0.25 Tablet: Each film coated tablet contains Ropinirole 0.25 mg as Ropinirole Hydrochloride USP

Pharmacology: Perkirol® (Ropinirole) is a non-ergoline dopamine agonist with high relative in vitro specificity and full intrinsic activity at the D_2 and D_3 dopamine receptor subtypes. The precise mechanism of action of **Perkirol®** (Ropinirole) as a treatment for Parkinson's disease & Restless Legs Syndrome (RLS) is unknown, although it is thought to be related to its ability to stimulate dopamine receptors.

Indication: Perkirol® is indicated for the treatment of the signs and symptoms of idiopathic Parkinson's disease. It is also indicated for the treatment of moderate-to-severe primary Restless Legs Syndrome (RLS).

Dosage and Administration: *Dosing for Parkinson's disease:* The recommended starting dose for Parkinson's disease is 0.25 mg three times daily. Based on individual patient therapeutic response and tolerability, if necessary, the dose should then be titrated with weekly increments as described in Table 1. Maximum recommended total daily dose of 24 mg (8 mg three times daily).

Table 1: Ascending-dose Schedule for Parkinson's disease

Week	Dosage	Total Daily Dose
1	0.25 mg 3 times daily	0.75 mg
2	0.5 mg 3 times daily	1.50 mg
3	0.75 mg 3 times daily	2.25 mg
4	1 mg 3 times daily	3 mg

Dosing for Restless Legs Syndrome: The recommended adult starting dose for RLS is 0.25 mg once daily 1 to 3 hours before bedtime. After 2 days, if necessary, the dose can be increased to 0.5 mg once daily, and to 1 mg once daily at the end of the first week of dosing, then as shown in Table 2 as needed to achieve efficacy. Titration should be based on individual patient therapeutic response and tolerability, up to a maximum recommended dose of 4 mg daily.

Table 2: Dose Titration Schedule for RLS

Day/Week	Dosage to be taken once daily, 1 to 3 hours before bedtime
Days 1 and 2	0.25 mg
Days 3-7	0.5 mg
Week 2	1 mg
Week 3	1.5 mg
Week 4	2 mg
Week 5	2.5 mg
Week 6	3 mg
Week 7	4 mg

Precaution & Warning: Patients treated with Ropinirole have reported falling asleep while engaged in activities of daily living. Dopamine agonists in clinical trials and clinical experience appear to impair the systemic regulation of blood pressure, with resulting orthostatic hypotension.

Contraindication: It is contraindicated in patients known to have a hypersensitivity to Ropinirole.

Side effect: The most common side effects of Ropinirole include fainting, drowsiness, hallucinations, dizziness, nausea or vomiting, uncontrolled sudden movements, leg swelling, fatigue, confusion, headache, upset stomach, abdominal pain or discomfort, increased sweating etc.

Drug Interaction: Because Ropinirole is a dopamine agonist, it is possible that dopamine antagonists such as neuroleptics (phenothiazines, butyrophenones, thioxanthenes) or metoclopramide may reduce the efficacy of Ropinirole.

Use in pregnancy & lactation: Pregnancy category C. There is no adequate and well-controlled studies in pregnant women. It should be used during pregnancy only if the potential benefit outweighs the potential risk to the fetus. Ropinirole inhibits prolactin secretion in human and could potentially inhibit lactation.

Storage condition: Protect from light and moisture, store below 25° C. Keep out of the reach of children.

How supplied: Perkirol® 0.25 Tablet: Each box contains 50 Tablets in blister pack.

Manufactured by

SQUARE
PHARMACEUTICALS LTD.
BANGLADESH