

Perkirol[®]

Ropinirole

Composition

Perkirol[®] 0.25 Tablet: Each tablet contains Ropinirole 0.25 mg as Ropinirole Hydrochloride USP

Perkirol[®] 2 Tablet: Each tablet contains Ropinirole 2 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 D₂ and D₃ 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 30⁰ C. Keep out of the reach of children.

How supplied

Perkirol[®] 0.25 Tablet: Each box contains 50 Tablets in blister pack.

Perkirol[®] 2 Tablet: Each box contains 30 Tablets in blister pack.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.

Pabna, Bangladesh

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