Restine® (Pramipexole dihydrochloride)

Category:

Dopamine Receptor Agonists, Non-Ergot

Pharmacokinetics:

Non-ergot dopamine agonists are rapidly absorbed. The absolute bioavailability is more than 90%. Steady-state concentrations are achieved within 2 days of dosing. Terminal half-life is about 8 to12 hours.
Urinary excretion is the major route of elimination.

Mechanism of action:

Non-ergot dopamine agonist for PD with high specificity at the D_2 subfamily of dopamine receptors, binding with higher affinity to D_3 than to D_2 or D_4 receptor subtypes.
The mechanism of action is believed to be related to its ability to stimulate dopamine receptors in the striatum.

Indications:

Parkinson disease (PD): For the treatment of the signs and symptoms of idiopathic PD.

Administration and Dosage:

May take with food to reduce the occurrence of nausea.
Initial treatment – Increase gradually from a starting dose of 0.375 mg/day given in 3 divided doses every 5 to 7 days to 4.5 mg/day in patients with Ccr > 60 mL/min.
Maintenance treatment – Pramipexole is effective and well tolerated over a dosage range of 1.5 to 4.5 mg/day administered in equally divided doses 3 times/day with or without concomitant levodopa (800 mg/day). When pramipexole is used in combination with levodopa, consider a reduction of the levodopa dosage.
Discontinuation – Discontinue over a period of 1 week.

Contraindications:

Hypersensitivity to the drug or any component of the product.

Precautions:

Monitoring: Monitor for signs and symptoms of orthostatic hypotension.
Dyskinesia: Dopamine receptor agonists may potentiate the dopaminergic side effects of levodopa and may cause or exacerbate pre-existing dyskinesia.
Decreasing the dose of levodopa may ameliorate this side effect.
CNS effects: Use concomitant CNS depressants with caution because of the possible additive sedative effects.

Pregnancy and breast feeding:

Pregnancy: Category C.
Lactation: It is not known whether these drugs are excreted in breast milk.

Side effects:

Adverse reactions occurring in at least 3% of patients with early PD (without levodopa) included the following: abdominal pain; abnormal vision; amnesia; angina; anorexia; anxiety; arthralgia; asthenia; back pain; bronchitis; chest pain; CHF; confusion; constipation; dehydration; depression; diarrhea; dizziness; drowsiness.
Adverse reactions occurring in at least 3% of patients with advanced PD (with levodopa) included the following: abdominal pain; accidental injury; accommodation abnormalities; akathisia; amnesia; arthritis; asthenia; chest pain; confusion; constipation; diarrhea; dizziness; dream abnormalities; dry mouth.

Drug Interactions:

Drugs that may affect dopamine receptors agonists include cimetidine; estrogen; ciprofloxacin; drugs eliminated via renal excretion; inhibitors of CYP1A2 and dopamine antagonists; dopamine agonists, such as neuroleptics (eg, phenothiazines, butyrophenones, thioxanthenes) or metoclopramide. Drugs that may be affected by dopamine receptor agonists include levodopa.

Packaging:

Restine® is available as 0.18 and 0.7 mg scored tablets in box of 30 tablets.

Storage:

- Store below 30 °C
- Protect from moisture and light
- Keep out of the reach of children