Only for the use of Medical Professionals

Parixol®

Pramipexole

Description

Parixol® is a preparation pramipexole. Pramipexole is a non-ergot dopamine agonist. It has high affinity for dopamine D2-like receptors with highest affinity at dopamine D_3 and D_2 receptors. Pramipexole's affinity to D_3 receptors might be responsible for its antidepressant activity.

Indication and usage

Parixol® is indicated for the treatment of

- Parkinson's disease, used alone or as an adjunct to levodopa with dopa-decarboxylase inhibitor
- Moderate to severe restless legs syndrome

Dose and administration

The recommended dose of Parixol® is as following.

Parkinson's disease: Initially 88 micrograms 3 times daily, dose doubled every 5–7 days if tolerated to 350 micrograms 3 times daily; further increased if necessary by 180 micrograms 3 times daily at weekly intervals
Maximum dose: 3.3 mg daily in 3 divided doses

During pramipexole dose titration and maintenance Levodopa dose should be reduced.

Restless legs syndrome: Initially 88 micrograms once daily 2–3 hours before bedtime, dose doubled every 4–7 days if necessary to 350 micrograms daily.
Maximum dose: 540 micrograms daily

Use in children

Pramipexole is not recommended for children below 18 years of age.

Use in pregnancy and lactation

The effect of pramipexole on pregnancy and lactation has not been investigated in humans so it should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus. Pramipexole inhibits secretion of prolactin in humans. The excretion of pramipexole into breast milk has not been studied in women so it should not be used during breast-feeding. However, if its use is unavoidable then breast-feeding should be discontinued.

Precautions

Caution should be taken in patients with psychotic disorder, ophthalmologic monitoring is recommended at regular intervals, severe cardiovascular disease and renal impairment.

Side effects

The common side effects are dizziness, dyskinesia, nausea, hypotension, abnormal dreams, confusion, constipation, delusion, hallucinations, headache, hyperkinesia, increased eating (binge eating, hyperphagia), insomnia, libido disorders, nausea, peripheral oedema, paranoia, pathological gambling, hypersexuality and other abnormal behaviour, somnolence, weight increase, sudden onset of sleep, pruritus and rash and other hypersensitivity.

Drug interactions
Pramipexole is the only dopamine agonist not appreciably metabolized by the P450 system which minimizes about possible drug-drug interactions. Cimetidine and amantadine may reduce the renal clearance of pramipexole. Sedating medicinal products or alcohol in combination with pramipexole may cause additive effects.

Contraindications
Pramipexole is contraindicated in patients with known Hypersensitivity to the active substance or to any of the excipients.

Overdose
There is no clinical experience with massive overdose. Symptoms of overdose are nausea, vomiting, hyperkinesia, hallucinations, agitation and hypotension. There is no established antidote. If signs of central nervous system stimulation are present, a neuroleptic agent may be indicated. Management of the overdose may require general supportive measures, along with gastric lavage, intravenous fluids, administration of activated charcoal and electrocardiogram monitoring.

Pharmaceutical precautions
Store in a cool and dry place. Protect from light.

Presentation
Parixol® 88 tablet : Each tablet contains Pramipexole 88mcg as hydrochloride.
Parixol® 180 tablet : Each tablet contains Pramipexole 180mcg as hydrochloride.

Packaging quantities
Parixol® 88 tablet : Each box contains 3 blister strips of 10 tablets.
Parixol® 180 tablet : Each box contains 3 blister strips of 10 tablets.

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