

Ropinirole

Traffic light classification- Amber 2 Information sheet for Primary Care Prescribers

CLINICAL INFORMATION

Key points/interactions

- Nausea is a common early side effect but usually responds to domperidone (10mg tds, or lowest effective dose – see [MHRA advice](#))
- For most patients slow release preparations are more convenient to take and provide smoother symptom control
- Dopamine agonists may cause compulsive/addictive behaviours such as gambling, compulsive shopping and hyper sexuality. Patients rarely recognise such changes as side effects and rarely report them unless specifically asked.

Licensed Indications

Treatment of Parkinson's disease. As initial treatment as monotherapy, in order to delay the introduction of levodopa or in combination with levodopa, throughout the disease, when the effect of levodopa wears off or becomes inconsistent and fluctuations in the therapeutic effect occur ("end of dose" or "on-off" type fluctuations).

Therapeutic Summary

As per the licensed indication.

NICE recommendations for the use of ropinirole in Parkinson's disease are:

- Consider a choice of dopamine agonists, levodopa or monoamine oxidase B (MAO-B) inhibitors for people in the early stages of Parkinson's disease whose motor symptoms do not impact their quality of life. Do not offer ergot-derived dopamine agonists as first-line treatment for Parkinson's disease.
- Offer a choice of dopamine agonists, MAO-B inhibitors or catechol-O-methyltransferase (COMT) inhibitors as an adjunct to levodopa for people with Parkinson's disease who have developed dyskinesia or motor fluctuations despite optimal levodopa therapy, after discussing:
 - the person's clinical circumstances, for example, their Parkinson's disease symptoms, comorbidities and risks from polypharmacy
 - the person's lifestyle circumstances, preferences, needs and goals
 - the potential benefits and harms of the different drug classes
- Choose a non-ergot-derived dopamine agonist in most cases, because of the monitoring that is needed with ergot-derived dopamine agonists. Only consider an ergot-derived dopamine agonist as an adjunct to levodopa for people with Parkinson's disease:
 - who have developed dyskinesia or motor fluctuations despite optimal levodopa therapy **and**
 - whose symptoms are not adequately controlled with a non-ergot-derived dopamine agonist.
- When treating nocturnal akinesia, consider levodopa or oral dopamine agonists. If the selected option is not effective or not tolerated, offer the other instead.

Medicines Initiation

Consultant neurologist/specialist experienced in the management of PD.

Dose Regimen

Modified Release tablets are preferred in order to avoid fluctuations in plasma levels. The usual dosing regimen is as follows:

- 2 mg MR once daily for the first week; this should be increased to 4 mg once daily from the second week of treatment
- If needed the daily dose may be increased by 2 mg at weekly or longer intervals up to a dose of 8 mg MR once daily.
- Over the next 3-5 years it is commonly necessary to gradually increase the dose to a maximum of three 8mg (24mg) ropinirole MR tablets taken together once a day.
- Consider slower titration for patients over 75 years.

- MR tablets should be taken once a day, at similar time each day with or after food. They must be swallowed whole and not be chewed, crushed or divided.

For dosing of the immediate release, product see BNF or [Summary of Product Characteristics](#).(SPC)

Duration of treatment

Ropinirole is a treatment for chronic disease and therefore course length can be many years. Antiparkinsonian drug therapy should never be stopped abruptly as this carries a small risk of neuroleptic malignant syndrome. See precautions section for discontinuation information.

Missed dose

Manufacturer advises if treatment is interrupted for one day or more, re-initiation by dose titration should be considered- consult SPC.

Contraindications

- Pregnancy and lactation
- Hypersensitivity to ropinirole or any of the excipients
- Severe renal impairment (creatinine clearance <30 ml/min) without regular haemodialysis. Hepatic impairment.

Precautions

- Elderly
- Severe cardiovascular disease- blood pressure monitoring required, see monitoring requirements
- Major psychotic disorders
- If it is necessary to discontinue ropinirole treatment, this should be done gradually by reducing the daily dose over one week.
- This medicinal product contains lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Monitoring

- Ask about gambling and other addictive behaviours. Patients may deny such symptoms when first asked about them.
- Blood pressure monitoring is recommended, particularly at the start of treatment, in patients with severe cardiovascular disease (in particular coronary insufficiency).

Adverse Effects

Side Effects	Action
Abdominal pain, dyspepsia, constipation	Usually transient. If persists discuss with neurologist/PD nurse specialist [PDNS]
Nausea & vomiting	Usually transient but may be quite severe. Unless very minor, prescribe domperidone 10mg TDS (or lowest effective dose- see MHRA) during dose titration; this can usually be stopped within a few weeks.
Sedation	Usually transient. Advise patients not to drive/operate machinery if affected. If persists discuss with neurologist/PDNS
Orthostatic hypotension	Usually transient. If persists discuss with neurologist/PDNS
Light-headedness, dizziness	Usually transient. If persists discuss with a neurologist.
Leg oedema	Rarely a major problem. Discuss with a neurologist if no other explanation is identified
Hallucinations, confusion	Discuss with neurologist/PDNS
Psychotic reactions (other than hallucinations), including delusion, paranoia, delirium.	Discuss with neurologist/PDNS
'Dopamine dysregulation syndrome' Manifests as a change in behaviour, typically with an obsessional, risk-taking, sexual or financial axis.	Discuss with neurologist/PDNS

Hypersensitivity reactions including urticaria, rash, angioedema.	Discontinue and discuss with neurologist/PDNS
Raised hepatic enzymes	Discuss with neurologist/PDNS

Clinically relevant medicine interactions and their management

Patients selected for treatment with ropinirole are almost certain to be taking concomitant medications for their Parkinson's disease. In the initial stages of ropinirole therapy, the patient should be monitored for unusual side effects or signs of potentiation of effect.

- **Neuroleptic medicinal products and other centrally acting dopamine antagonists** e.g. sulpiride, metoclopramide - may have an antagonistic effect if used with ropinirole. Avoid concomitant use.
- **Inhibitors of cytochrome P450 enzyme CYP1A2** e.g. ciprofloxacin, fluvoxamine, cimetidine - may lead to increased levels of ropinirole
- **Antihypertensives**– increased hypotensive effect.
- **Memantine** - enhanced effect.
- **Oestrogens** - increased plasma concentrations of ropinirole. Dosage adjustments may be required if HRT is introduced or stopped.
- **Smoking**- may decrease ropinirole levels through CYP1A2 induction. Consider dose adjustments if the patient starts or stops smoking.

For further information on contraindications, precautions, adverse effects and interactions refer to the BNF or [Summary of Product Characteristics](#).

Information given to the patient

Patients (and their family members and carers) should be given information on the following:

- The risk of excessive daytime sleepiness and sudden onset of sleep and the need to exercise caution when driving or operating machinery. If affected patients should refrain from driving or operating machinery until these effects have stopped occurring.
- The increased risk of developing impulse control disorders when taking dopamine agonist therapy and that these may be concealed by the person affected. Advice should be given about who to contact if impulse control disorders develop.
- The risk of psychotic symptoms (hallucinations and delusions) with all Parkinson's disease treatments (and the higher risk with dopamine agonists).

Products available

Ropinirole immediate-release and modified-release tablet.

Safe Practice

Ropinirole has been confused with risperidone; care must be taken to ensure the correct drug is prescribed and dispensed.

An estimate of the potential medicine costs (and any additional costs) to primary care

Ipinnia XL 2mg £5.64 x 28 tablets

Ropinirole MR 2mg £6.20 x 28 tablets (generic and other brands)

Ipinnia XL 3mg £8.46 x 28 tablets

Ipinnia XL 4mg £11.29 x 28 tablets

Ropinirole MR 4mg £12.50 x 28 tablets (generic and other brands)

Ipinnia XL 6mg £15.32 x 28 tablets

Ipinnia XL 8mg £18.95 x 28 tablets

Ropinirole MR 8mg £21.00 x 28 tablets (generic and other brands)

Ropinirole 2mg £19.00 x 28 tablets

REFERENCES

British National Formulary via NICE. [Ropinirole](#) [Accessed 23/05/2024].

[Requip XL Summary of Product Characteristics](#). Last updated 31 Jan 2024. [Accessed 23/05/2024].

[NICE NG71 Parkinson's disease in adults](#), July 2017. [Accessed 23/05/2024].

MHRA Drug Safety Update: Domperidone: risks of cardiac side effects, [May 2014](#) [Accessed 23/05/2024].

[Drug Tariff](#) [Accessed 23/05/2024].