

INFORMATION FOR THE USER

Ipinnia XL 2 mg prolonged-release tablets
Ipinnia XL 3 mg prolonged-release tablets
Ipinnia XL 4 mg prolonged-release tablets
Ipinnia XL 6 mg prolonged-release tablets
Ipinnia XL 8 mg prolonged-release tablets



Ropinirole

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- The full name of this medicine is Ipinnia XL 2 mg, 3 mg, 4 mg, 6 mg and 8 mg Prolonged-release Tablets but within the leaflet it will be referred to as Ipinnia XL.

What is in this leaflet

1. What Ipinnia XL is and what it is used for
2. What you need to know before you take Ipinnia XL
3. How to take Ipinnia XL
4. Possible side effects
5. How to store Ipinnia XL
6. Contents of the pack and other information

1. What Ipinnia XL is and what it is used for

The active ingredient in Ipinnia XL is ropinirole, which belongs to a group of medicines called dopamine agonists. Dopamine agonists affect the brain in a similar way to a natural substance called dopamine.

Ipinnia XL is used to treat Parkinson's disease. People with Parkinson's disease have low levels of dopamine in some parts of their brains. Ropinirole has effects similar to those of natural dopamine, so it helps to reduce the symptoms of Parkinson's disease.

You can take Ipinnia XL either on its own or along with L-dopa (see section 4 of this leaflet for more details). Ipinnia XL should be prescribed and your progress monitored by a doctor with experience in the treatment of Parkinson's disease.

2. What you need to know before you take Ipinnia XL

Do not take Ipinnia XL

- if you are **allergic** (hypersensitive) to ropinirole or any of the other ingredients of this medicine (listed in section 6)
- if you have a **serious kidney** disease
- if you have a **liver** disease

Tell your doctor if you think any of these may apply to you.

Warnings and precautions

Take special care with Ipinnia XL if you:

- are pregnant or think you may be pregnant
- are breast-feeding
- are under 18 years old
- have a serious heart complaint
- have a history of or currently have a serious mental health problem
- have a history of or have experienced any unusual urges and/or behaviours (such as excessive gambling or excessive sexual behaviour, see section 4)
- have an intolerance to some sugars (such as lactose).

Tell your doctor if you experience symptoms such as depression, apathy, anxiety, lack of energy, sweating or pain after stopping or reducing your ropinirole treatment (called dopamine agonist withdrawal syndrome or DAWS). If the problems persist more than a few weeks, your doctor may need to adjust your treatment.

Tell your doctor if you think any of these may apply to you. Your doctor may decide that Ipinnia XL is not suitable for you, or that you need extra check-ups while you are taking it. You also need to be careful with Ipinnia XL if you drive or operate machinery. Please read the warning in section 3 of this leaflet.

While you are taking Ipinnia XL

Tell your doctor if you or your family/carer notices that you are developing urges or cravings to behave in ways that are unusual for you and you cannot resist the impulse, drive or temptation to carry out certain activities that could harm yourself or others. These are called impulse control disorders and can include behaviours such as addictive gambling, excessive eating or spending, an abnormally high sex drive or an increase in sexual thoughts or feelings. Your doctor may need to adjust or stop your dose.

Smoking and Ipinnia XL

Tell your doctor if you start smoking, or give up smoking, while you are taking Ipinnia XL. Your doctor may need to adjust your dose.

Other medicines and Ipinnia XL

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, including any herbal remedies or medicines obtained without a prescription. Also remember to tell your doctor or pharmacist if you begin taking a new medicine while you are taking Ipinnia XL.

Some medicines can affect the way Ipinnia XL works, or make it more likely that you will have side effects. Ipinnia XL can also affect the way some other medicines work. These include:

- the anti-depressant fluvoxamine
- medication for other mental health problems, for example sulphiride
- HRT (hormone replacement therapy)
- cimetidine, used in the treatment of stomach ulcers

- metoclopramide, which is used to treat nausea and heartburn
- the antibiotics ciprofloxacin or enoxacin
- any other medicine for Parkinson's disease.

Tell your doctor if you are taking, or have recently taken, any of these. Remember to tell your doctor or nurse if you start taking any other medicine while you're taking Ipinnia XL.

Ipinnia XL with food and drink

You can take Ipinnia XL with or without food, as you prefer. Because high fat foods might increase the amount of ropinirole absorbed by your body, it is recommended that you do not take Ipinnia XL at the same time as a high fat meal.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Ipinnia XL is not recommended if you are pregnant, unless your doctor advises that the benefit to you of taking Ipinnia XL is greater than the risk to your unborn baby.

Your doctor will also advise you if you are breast-feeding or planning to do so. Ipinnia XL is not recommended if you are breast-feeding, as it can affect your milk production. Your doctor may advise you to stop taking Ipinnia XL.

Driving and using machines

Ipinnia XL can make you feel drowsy or dizzy. It can make people feel extremely sleepy, and it sometimes makes people fall asleep very suddenly without warning.

If you could be affected: do not drive, do not operate machines and do not put yourself in any situation where feeling sleepy or falling asleep could put you (or other people) at risk of serious injury or death. Do not take part in these activities until you are no longer affected.

Ropinirole can cause hallucinations (seeing, hearing or feeling things that are not there). If affected, do not drive or use machines.

Talk to your doctor or nurse if this causes problems for you.

Ipinnia XL contain lactose and castor oil

Ipinnia XL contains a type of sugar called lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Ipinnia XL. Ipinnia XL contains castor oil. May cause stomach upset and diarrhoea.

3. How to take Ipinnia XL

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Use in children and adolescents

Do not give Ipinnia XL to children. Ipinnia XL is not normally prescribed for people under 18 years of age.

You may be given Ipinnia XL on its own to treat the symptoms of your Parkinson's disease. You may also be given Ipinnia XL with another medicine called L-dopa (also called levodopa). If you are taking L-dopa you may experience some uncontrolled jerky movements (dyskinesias) when you first start taking Ipinnia XL. Tell your doctor if this happens, as your doctor may need to adjust the dose of L-dopa you are taking.

Tell your doctor if you or your family notices that you are developing any unusual behaviours (such as an unusual urge to gamble or increased sexual urges and/or behaviours) while you are taking Ipinnia XL. Your doctor may need to adjust your dose.

How much Ipinnia XL will you need to take?

It may take a while to find out the best dose of Ipinnia XL for you.

The recommended starting dose of Ipinnia XL is 2 mg once daily for the first week. Your doctor may increase your dose to 4 mg of Ipinnia XL once daily, from the second week of treatment. If you are very elderly, your doctor may increase your dose more slowly. After that, the doctor may adjust your dose until you are taking the dose that is best for you.

Some people take up to 24 mg of Ipinnia XL each day.

If at the start of your treatment you experience side effects that you find difficult to tolerate, speak to your doctor. Your doctor may advise you to switch to a lower dose of ropinirole film-coated (immediate-release) tablets which you will take three times a day.

It may take a few weeks for Ipinnia XL to work for you.

Do not take any more Ipinnia XL than your doctor has recommended.

Method of administration

Take Ipinnia XL once a day, at the same time each day.

Swallow your Ipinnia XL tablet(s) whole, with a glass of water. Do not break, chew or crush them. If you do so, there is a danger you could overdose, because the medicine will be released into your body too quickly.

Ipinnia XL tablets are designed to release the drug into your body over a 24 hour period. If the tablets pass through your body in less than 24 hours the medicine may not be completely released. You may see tablets in your stool. If this happens, let your doctor know.

If you are switching from ropinirole film-coated (immediate-release) tablets

Your doctor will base your dose of Ipinnia XL on the dose of ropinirole film-coated (immediate-release) tablets you were taking.

You will take the same or similar daily dose of Ipinnia XL to your previous dose of ropinirole film-coated (immediate-release) tablets but you will only take Ipinnia XL once a day.

Take your ropinirole film-coated (immediate-release) tablets as normal the day before you switch. Then take your Ipinnia XL the next morning and do not take any more ropinirole film-coated (immediate-release) tablets.

Your doctor or nurse will be monitoring your progress closely after switching to Ipinnia XL. If there is any change in the control of your symptoms before your next appointment, talk to your doctor or nurse as soon as possible in case dose adjustment is needed.

If you take more Ipinnia XL than you should

Contact a doctor or pharmacist immediately. If possible, show them the Ipinnia XL pack.

Someone who has taken an overdose of Ipinnia XL may have any of these symptoms: feeling sick (nausea), being sick (vomiting), dizziness (a spinning sensation), feeling drowsy, mental or physical tiredness, fainting, hallucinations.

If you forget to take Ipinnia XL

Do not take a double dose to make up for a forgotten tablet.

If you have missed taking Ipinnia XL for one day or more, ask your doctor for advice on how to start taking it again.

If you stop taking Ipinnia XL

Do not stop taking Ipinnia XL without advice. Take Ipinnia XL for as long as your doctor recommends. Do not stop unless your doctor advises you to. If you suddenly stop taking Ipinnia XL, your Parkinson's disease symptoms may quickly get much worse.

A sudden stop could cause you to develop a medical condition called neuroleptic malignant syndrome which may represent a major health risk. The symptoms include: akinesia (loss of muscle movement), rigid muscles, fever, unstable blood pressure, tachycardia (increased heart rate), confusion, depressed level of consciousness (e.g. coma).

If you need to stop taking Ipinnia XL, your doctor will reduce your dose gradually.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The side effects of Ipinnia XL are more likely to happen when you first start taking it, or when your dose has just been increased. They are usually mild, and may become less troublesome after you have taken the dose for a while. If you are worried about side effects, talk to your doctor.

Very common:

(affects more than 1 user in 10)

- fainting
- feeling drowsy
- feeling sick (nausea).

Common:

(affects 1 to 10 users in 100)

- falling asleep very suddenly without feeling sleepy first (sudden sleep onset episodes)
- hallucinations ("seeing" things that are not really there)
- being sick (vomiting)
- feeling dizzy (a spinning sensation)
- heartburn
- stomach pain
- constipation
- swelling of the legs, feet or hands.

Uncommon:

(affects 1 to 10 users in 1,000)

- feeling dizzy or faint, especially when you stand up suddenly (this is caused by a drop in blood pressure)
- feeling very sleepy during the day (extreme somnolence)
- mental problems such as delirium (severe confusion), delusions (unreasonable ideas) or paranoia (unreasonable suspicions).

Very rare

(affects 1 in 10,000)

- changes in liver function, which have shown up in blood tests.
- hypersensitivity reactions including itchy skin rash, swollen face, lips, throat or tongue which may cause difficulty swallowing or breathing, rash and itching.

After stopping or reducing your Ipinnia XL treatment: Depression, apathy, anxiety, lack of energy, sweating or pain may occur (called dopamine agonist withdrawal syndrome or DAWS).

Not known:

(frequency cannot be estimated from the available data)

Inability to resist the impulse, drive or temptation to perform an action that could be harmful to you or others, which may include:

- Strong impulse to gamble excessively despite serious personal or family consequences.
- Altered or increased sexual interest and behaviour of significant concern to you or to others, for example, an increased sexual drive.
- Uncontrollable excessive shopping or spending
- Binge eating (eating large amounts of food in a short time period) or compulsive eating (eating more food than normal and more than is needed to satisfy your hunger).
- act in an aggressive manner.
- excessive use of Ipinnia XL (craving for large doses of dopaminergic drugs in excess of that required to control motor symptoms, known as dopamine dysregulation syndrome).

Tell your doctor if you experience any of these behaviours; they will discuss ways of managing or reducing the symptoms.

If you are taking Ipinnia XL with L-dopa

People who are taking Ipinnia XL with L-dopa may develop other side effects over time:

- uncontrolled jerky movements (dyskinesias) are a very common side effect. If you are taking L-dopa you may experience some uncontrollable movements (dyskinesias) when you first start taking Ipinnia XL. Tell your doctor if this happens, as your doctor may need to adjust the doses of the medicines you are taking.
- feeling confused is a common side effect.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ipinnia XL

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister foil after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Ipinnia XL contains

-The active substance is ropinirole. Each prolonged-release tablet contains 2 mg, 3 mg, 4 mg, 6 mg or 8 mg of ropinirole (as hydrochloride).

-The other ingredients are: hypromellose, croscarmellose sodium, maltodextrin; lactose monohydrate, hydrogenated castor oil, colloidal anhydrous silica, magnesium stearate; pigment blend:

2 mg tablets: iron oxide red (E172), iron oxide yellow (E172), lactose monohydrate, 3 mg tablets: lactose monohydrate, indigo carmine aluminium lake (E132), carmine (E120), 4 mg & 8 mg tablets: iron oxide red (E172), iron oxide yellow (E172), lactose monohydrate, iron oxide black (E172). 6 mg tablets: do not contain pigment blend.

What Ipinnia XL looks like and contents of the pack

Ipinnia XL 2 mg prolonged-release tablets are pink, mottled and oval with 2x debossed on one side.

Ipinnia XL 3 mg prolonged-release tablets are purple, mottled and oval with 3x debossed on one side.

Ipinnia XL 4 mg prolonged-release tablets are brown, mottled and oval with 4x debossed on one side.

Ipinnia XL 6 mg prolonged-release tablets are white and oval with 6x debossed on one side.

Ipinnia XL 8 mg prolonged-release tablets are dark pink, mottled and oval with 8x debossed on one side.

Pack sizes:

Ipinnia XL prolonged-release tablets are available in blister packs of 21, 28, 30, 42, 56, 84 and 90 prolonged release tablets.

Not all pack sizes may be available.

Marketing Authorisation Holder

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