

Package Leaflet: Information for the user

Repinex XL 2mg prolonged-release tablets

Repinex XL 4mg prolonged-release tablets

Repinex XL 8mg 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

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

The active substance in Repinex 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.

Repinex 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.

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

Do not take Repinex XL:

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

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

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine:

- if you are **pregnant** or think you may be pregnant.
- if you are **breast-feeding**.
- if you are **under 18 years old**.
- if you have a **serious heart complaint**.
- if you have a **serious mental health problem**.
- if you have experienced any **unusual urges and/or behaviours** (see section 4).
- if you 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 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**.

Tell your doctor if you or your family/carer notices that you are developing episodes of overactivity, elation or irritability (symptoms of mania). These may occur with or without the symptoms of impulse control disorders (see above). **Your doctor may need to adjust or stop your dose**.

Tell your doctor or nurse if you think any of these may apply to you. Your doctor or nurse may decide that this medicine is not suitable for you or that you need extra check-ups while you are taking it.

While you are taking Repinex XL

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 Repinex XL. Your doctor may need to adjust or stop your dose.

Smoking and Repinex XL

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

Other medicines and Repinex XL

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Remember to tell your doctor or nurse if you start taking any other medicine while you are taking Repinex XL.

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

These include:

- the **anti-depressant fluvoxamine**
- medicine for other **mental health problems**, for example **sulpiride**
- **HRT** (hormone replacement therapy)
- **metoclopramide**, which is used to treat nausea and heartburn
- the **antibiotics ciprofloxacin** or **enoxacin**
- any other medicine for Parkinson's disease

Tell your doctor or nurse if you are taking, or have recently taken, any of these.

You will require additional blood tests if you are taking these medicines with Repinex XL:

- Vitamin K antagonists (used to reduce blood clotting) such as Warfarin (coumadin).

Repinex XL with food and drink

You can take this medicine with or without food, as you prefer.

Pregnancy and breast-feeding

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

Repinex XL is not recommended if you are breast-feeding, as it can affect your milk production.

Tell your doctor immediately, if you are pregnant, think you may be pregnant, or are planning to have a baby. Your doctor will advise you if you are breast-feeding or planning to do so. Your doctor may advise you to stop taking Repinex XL.

Driving and using machines

This medicine can make you feel drowsy. Ropinirole can cause hallucinations (seeing, hearing or feeling things that are not there). If affected, do not drive or use machines.

It can make people feel extremely sleepy and it sometimes makes people **fall asleep very suddenly without warning**.

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

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 sure you are not affected.

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

Repinex XL contains lactose

Repinex XL 2mg

This medicine contains a sugar called **lactose**. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Repinex XL contains sunset yellow (E110)

Repinex XL 4mg

This medicine contains a colouring agent called **sunset yellow (E110)**, which may cause allergic reactions.

Repinex XL contains sodium

This medicine contains less than 1 mmol sodium (23mg) per prolonged-release tablet, that is to say essentially 'sodium-free'.

3. How to take Repinex 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.

You may be given this medicine on its own to treat the symptoms of your Parkinson's disease, or you may be given Repinex XL as well as another medicine called L-dopa (also called levodopa).

If you are taking L-dopa, you may experience some uncontrollable movements (dyskinesias) when you first start taking this medicine. Tell your doctor if this happens, as your doctor may need to adjust the dose of the medicines you are taking.

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

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

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

How much Repinex XL will you need to take?

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

The recommended starting dose is 2mg once daily for the first week. Your doctor may increase your dose to 4mg of Repinex XL prolonged-release tablets 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 24mg of Repinex XL prolonged-release tablets 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.

Do not take more Repinex XL than your doctor or nurse has recommended.

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

Taking your dose of Repinex XL

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

Swallow your Repinex XL prolonged-release tablet(s) whole, with a glass of water.

Do not break, chew or crush the prolonged-release tablet(s) - if you do, there is a danger you could overdose, because the medicine will be released into your body too quickly.

Repinex XL prolonged-release tablets are designed to release the medicine over a 24 hour period. If you have a condition where the medicine passes through your body too quickly, e.g., diarrhoea, the tablets may not dissolve and work properly. If you notice tablets in your stool, let your doctor know as soon as possible.

Use in children and adolescents

Do not give this medicine to children. Repinex XL is not normally prescribed for people under 18.

If you take more Repinex XL than you should

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

Someone who has taken an overdose of Repinex 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 Repinex XL

Do not take extra prolonged-release tablets or a double dose to make up for a missed dose.

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

If you stop taking Repinex XL

Do not stop taking Repinex XL without advice.

Take Repinex XL for as long as your doctor or nurse recommends.

Do not stop unless your doctor or nurse advises you to.

If you suddenly stop taking this medicine, 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 this medicine, your doctor or nurse will reduce your dose gradually.

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

4. Possible side effects

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

The side effects of this medicine 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 or nurse.

Very common side effects (may affect more than 1 in 10 people)

- fainting
- feeling drowsy
- feeling sick (nausea)

Common side effects (may affect up to 1 in 10 people)

- 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 side effects (may affect up to 1 in 100 people)

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

Some patients may have the following side effects (frequency not known: cannot be estimated from the available data)

- allergic reactions such as red, itchy swellings on the skin (hives), swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, rash or intense itching (see section 2)
- changes in liver function, which have shown up in blood tests
- act in an aggressive manner
- excessive use of Repinex XL (craving for large doses of dopaminergic drugs in excess of that required to control motor symptoms, known as dopamine dysregulation syndrome)
- inability to resist that 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 is needed to satisfy your hunger).
- episodes of overactivity, elation or irritability
- after stopping or reducing your Repinex XL treatment: depression, apathy, anxiety, fatigue, sweating or pain may occur (called dopamine agonist withdrawal syndrome or DAWS).
- spontaneous penile erection

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

If you are taking Repinex XL with L-dopa

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

- uncontrollable 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 Repinex XL. Tell your doctor if this happens, as your doctor may need to adjust the dose 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 (website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Repinex 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 blister, the bottle and the carton after 'EXP'. The expiry date refers to the last day of that month.

Do not store above 25°C.

HDPE bottle: after first opening, use within 60 days.

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 Repinex XL contains

The active substance is ropinirole.

Each prolonged-release tablet contains 2mg, 4mg or 8mg ropinirole (as hydrochloride).

The other ingredients are:

- **tablet cores:** Ammonio Methacrylate Copolymer Type B, Hypromellose, Sodium lauryl sulfate (E487), Copovidone, Magnesium stearate.
- **film coats:**

2mg prolonged-release tablet	Hypromellose, iron oxide red (E172), lactose monohydrate, titanium dioxide (E171), triacetin
4mg prolonged-release tablet	Macrogol 400, hypromellose, sunset yellow aluminium lake (E110), titanium dioxide (E171), indigo carmine aluminium lake (E132)
8mg prolonged-release tablet	Hypromellose, iron oxide red (E172), iron oxide black (E172), iron oxide yellow (E172), macrogol 400, titanium dioxide (E171)

What Repinex XL looks like and contents of the pack

Repinex XL 2mg: pink prolonged-release round biconvex tablets 6.8 ± 0.1 mm in diameter and 5.5 ± 0.2 mm in thickness.

Repinex XL 4mg: light brown prolonged-release oval biconvex tablets $12.6 \times 6.6 \pm 0.1$ mm in diameter and 5.3 ± 0.2 mm in thickness.

Repinex XL 8mg: red prolonged-release oval biconvex tablets $19.2 \times 10.2 \pm 0.2$ mm in diameter and 5.2 ± 0.2 mm in thickness.

All strengths are supplied in white opaque PVC/PCTFE- Aluminium foil blisters and white opaque HDPE bottles with white cylindrical caps of polypropylene with three breakpoints on the tamper-evident ring and aperture of desiccant insert.

Pack sizes:

B blister: 7, 21, 28, 30, 42, 84, 90, 100 prolonged-release tablets
Bottle: 7, 21, 28, 30, 42, 84, 90, 100 prolonged-release tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Aspire Pharma Ltd
Unit 4, Rotherbrook Court
Bedford Road
Petersfield
Hampshire
GU32 3QG
United Kingdom

Manufacturer

Pharmathen SA
6 Dervenakion Str
153 51, Pallini Attiki
Greece

or

Pharmathen International SA
Industrial Park Sapes
Rodopi Prefecture
Block No 5
Rodopi 69300
Greece

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