

Package leaflet: Information for the user
ROPIQUAL XL 2 mg prolonged-release tablets
ROPIQUAL XL 4 mg prolonged-release tablets
ROPIQUAL 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 other people. 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.

What is in this leaflet:

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

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

ROPIQUAL XL prolonged-release tablets are used to treat Parkinson's disease.

The active ingredient in ROPIQUAL 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.

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 ROPIQUAL XL either on its own or along with L-dopa (see section 4 of this leaflet for more details). ROPIQUAL 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 ROPIQUAL XL

Do not take ROPIQUAL 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 ROPIQUAL XL:

- 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 history of or currently have a **serious mental health problem**
- if you have a history of or have experienced **any unusual urges and/or behaviours** (such as excessive gambling or excessive sexual behaviour, 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, fatigue, sweating or pain** after stopping or reducing your ROPIQUAL XL treatment (called dopamine agonist withdrawal syndrome or DAWS). If the problems persist more than a few weeks, your doctor may need to adjust your dose.

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 over activity, 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 ROPIQUAL 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 ROPIQUAL XL if you drive or operate machinery. **Please read the warning in section 3 of this leaflet.**

Smoking and ROPIQUAL XL

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

Other medicines and ROPIQUAL XL

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including any herbal remedies or other medicines you obtained without a prescription.

Remember to tell your doctor or pharmacist if you begin taking a new medicine while you are taking ROPIQUAL XL.

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

These include:

- the **anti-depressant fluvoxamine**
- medication for other **mental health problems**, for example **sulpride**

- **HRT** (hormone replacement therapy)
- **metoclopramide**, which is used to treat **nausea and heartburn**
- cimetidine, used in the treatment of stomach ulcers
- 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.

Remember to tell your doctor or nurse if you start taking any other medicine while you're taking ROPIQUAL XL.

ROPIQUAL XL with food and drink

You can take ROPIQUAL 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 ROPIQUAL XL at the same time as a high fat meal.

Pregnancy, breast-feeding and fertility
ROPIQUAL XL is not recommended if you are pregnant, unless your doctor advises that the benefit to you of taking ROPIQUAL XL is greater than the risk to your unborn baby.

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

Tell your doctor immediately if you are pregnant, if you think you might be pregnant, or if you are planning to become pregnant. Your doctor will also advise you if you are breast feeding or planning to do so. Your doctor may advise you to stop taking ROPIQUAL XL.

Driving and using machines

ROPIQUAL 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**.

Ropinirole 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 no longer affected.

Talk to your doctor if this causes problems for you.

Information on sodium content

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

ROPIQUAL XL 2 mg prolonged-release tablets contain 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 medicinal product.

ROPIQUAL XL 4 mg prolonged-release tablet contain the colouring agent **sunset yellow**, which may cause allergic reactions.

3. How to take ROPIQUAL 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.

Do not give ROPIQUAL XL to children.

ROPIQUAL XL is not normally prescribed for people under 18.

You may be given ROPIQUAL XL on its own to treat the symptoms of your Parkinson's disease or you may be given ROPIQUAL XL as well as another medicine called L-dopa (*also called levodopa*). ROPIQUAL XL should be prescribed and your progress monitored by a doctor with experience in the treatment of Parkinson's disease.

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

ROPIQUAL XL are designed to release drug 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.

How much ROPIQUAL XL will you need to take?

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

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

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

Taking your dose of ROPIQUAL XL
Take ROPIQUAL XL once a day, at the same time each day.

Swallow your ROPIQUAL 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.



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

Your doctor or nurse will base your dose of ROPIQUAL XL prolonged-release tablets on the dose of ropinirole film-coated (immediate-release) tablets you were taking. You will take the same or similar daily dose of ROPIQUAL XL to your previous dose of Ropinirole film-coated (immediate release) tablets but you will only take ROPIQUAL XL **once a day**.

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

If you take more ROPIQUAL XL than you should

Contact a doctor or pharmacist immediately. If possible, show them the ROPIQUAL XL pack. Someone who has taken an overdose of ROPIQUAL 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 ROPIQUAL XL

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

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

If you stop taking ROPIQUAL XL

Do not stop taking ROPIQUAL XL without advice.

Take ROPIQUAL XL for as long as your doctor recommends. Do not stop unless your doctor advises you to.

If you suddenly stop taking ROPIQUAL 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 ROPIQUAL 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 ROPIQUAL 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 side effects

These may affect **more than 1 in 10 people** taking ROPIQUAL XL:

- fainting
- feeling drowsy
- feeling sick (nausea)

Common side effects

These may affect **up to 1 in 10 people** taking ROPIQUAL XL:

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

Uncommon side effects

These may affect **up to 1 in 100 people** taking ROPIQUAL XL:

- 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
- Changes in **liver function**, which have shown up in blood tests
- Act in an aggressive manner
- Excessive use of ROPIQUAL 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 normal and more than is needed to satisfy your hunger).
- Episodes of overactivity, elation or irritability
- Depression, apathy, anxiety, lack of energy, sweating or pain may occur (called dopamine agonist withdrawal syndrome or DAWS) after stopping or reducing your ROPIQUAL XL treatment.
- 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 ROPIQUAL XL with L-dopa

People who are taking ROPIQUAL 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 ROPIQUAL 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at 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 ROPIQUAL 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, blister and bottle after EXP. The expiry date refers to the last day of that month.

Store ROPIQUAL XL below 25°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 ROPIQUAL XL contains

The active substance in ROPIQUAL XL is ropinirole.

Each prolonged release tablet contains ropinirole hydrochloride equivalent to 2 mg, 4mg or 8 mg ropinirole.

The other ingredients are:

- *tablet core:* Ammonio methacrylate copolymer, Type B, hypromellose, sodium lauryl sulfate, copovidone, magnesium stearate.

- *Tablet coating:*

2mg:	Hypromellose (E464), iron oxide red (E172), lactose monohydrate, titanium dioxide (E171), triacetin.
4mg:	Macrogol 400, hypromellose (E464), sunset yellow (E110), titanium dioxide (E171), indigo carmine (E132).
8mg:	Hypromellose (E464), iron oxide red (E172), iron oxide black (E172), iron oxide yellow (E172), macrogol 400, titanium dioxide (E171).

What ROPIQUAL XL looks like and contents of the pack

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

ROPIQUAL XL 4mg : light brown prolonged-release oval biconvex tablets with dimensions 12.6*6.6 ± 0.1 and 5.3 ± 0.2 mm in thickness.

ROPIQUAL XL 8mg : red prolonged-release oval biconvex tablets with dimensions 19.2*10.2 ± 0.2 mm and 5.2 ± 0.2 mm in thickness .

Pack sizes:

All strengths are supplied in white opaque PVC/PCTFE-Aluminium foil blisters.

2mg prolonged-release tablets:

White opaque PVC/PCTFE-Aluminum foil blister packs of 28, 30, 42 and 84 tablets.

4 mg prolonged-release tablets:

White opaque PVC/PCTFE-Aluminum foil blister packs of 28, 30 and 84 tablets.

8 mg prolonged-release tablets:

White opaque PVC/PCTFE-Aluminum foil blister packs of 28, 30 and 84 tablets.

Not all pack sizes may be marketed.

Marketing Authorization Holder:

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West End Road
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United Kingdom

Manufacturer:

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