

Package Leaflet: Information for the User

Requip® XL 8mg

prolonged-release tablets

(ropinirole hydrochloride)

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, nurse specialist or pharmacist.

This medicine has been prescribed for you only. Don't 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, nurse or pharmacist. This includes any possible side effects not listed in this leaflet.

See section 4.

The name of your medicine is Requip XL 8mg prolonged-release tablets but will be referred to as Requip XL throughout this leaflet. Please note that this leaflet also contains information about other strengths Requip XL 2mg and 4mg prolonged-release tablets

What is in this leaflet

- 1 What Requip XL is and what it is used for
- 2 What you need to know before you take Requip XL
- 3 How to take Requip XL
- 4 Possible side effects
- 5 How to store Requip XL
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1 What Requip XL is and what it is used for

Requip XL is used to treat Parkinson's disease. The active ingredient in Requip 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 Requip XL (like Requip) either on its own or along with L-dopa (see section 4 of this leaflet for more details). Requip 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 Requip XL

Do not take Requip 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 Requip 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 Requip 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 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 Requip XL isn't suitable for you, or that you need extra check-ups while you're taking it.

You also need to be careful with Requip XL if you drive or operate machinery. **Please read the warning in section 3 of this leaflet.**

Other medicines and Requip XL

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

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

These include:

- the **anti-depressant, fluvoxamine**
- **HRT** (hormone replacement therapy)
- medication for other **mental health problems**, for example **sulpiride**
- **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're 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 Requip XL.

Requip XL with food and drink

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

Pregnancy and breast-feeding

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

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

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.

Driving and using machines

Requip 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.**

Requip XL 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: **don't drive, don't operate machines** and **don't** put yourself in any situation where feeling sleepy or falling asleep could put you (or other people) at risk of serious injury or death. Don't take part in these activities until you are sure you're not affected.

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

Important Information about some of the ingredients in Requip XL

Requip XL contains lactose, sunset yellow and sodium

Requip XL contains a sugar called **lactose**.

If you have been told that you have an intolerance to some sugars, contact your doctor or nurse before taking Requip XL.

The 4mg tablets contain a colouring called **sunset yellow** (E110), which may cause allergic reactions. Requip XL contains less than 1mmol sodium (23mg) per tablet, that is to say essentially 'sodium-free'.

Smoking and Requip XL

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

3 How to take Requip XL

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

Do not give Requip XL to children. Requip XL is not normally prescribed for people under 18.

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

Requip 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 Requip 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 Requip XL. Your doctor may need to adjust your dose.

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

Your doctor or nurse will base your dose of Requip XL on the dose of Requip you were taking. You will take the same or similar daily dose of Requip XL to your previous dose of Requip but you will only take Requip XL **once a day.**

Take your Requip as normal the day before you switch. Then take your Requip XL on the next day and don't take any more Requip.

Your doctor or nurse will be monitoring your progress closely after switching to Requip 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.

How much Requip XL will you need to take?

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

The recommended starting dose of Requip XL tablets is 2mg once daily for the first week. Your doctor may increase your dose to 4mg of Requip XL 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 Requip XL 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 Requip film-coated (immediate-release) tablets which you will take three times a day.

Don't take more Requip XL than your doctor or nurse has recommended.

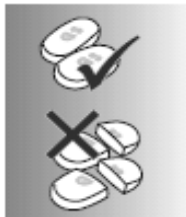
It may take a few weeks for Requip XL to work for you.

Taking your dose of Requip XL

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

Swallow your Requip XL tablets whole, with a glass of water.

Don't break, chew or crush the tablets - if you do, there's a danger you could overdose, because the medicine will be released into your body too quickly.



Requip 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 take more Requip XL than you should

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

Someone who has taken an overdose of Requip 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 Requip XL

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

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

If you stop taking Requip XL

Don't stop taking Requip XL without advice.

Take Requip XL for as long as your doctor or nurse recommends. Don't stop unless your doctor or nurse advises you to.

If you suddenly stop taking Requip 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 Requip XL, your doctor or nurse will reduce your dose gradually.

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

4 Possible side effects

Like all medicines, this medicine can have side effects, but not everyone gets them.

The more common side effects of Requip 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've taken the dose for a while. If you're 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 (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:

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
- 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 Requip 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 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).
- episodes of overactivity, elation or irritability
- Spontaneous penile erection
- Depression, apathy, anxiety, lack of energy, sweating or pain may occur (called dopamine agonist withdrawal syndrome or DAWS) after stopping or reducing your Requip XL treatment.

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

If you're taking Requip XL with L-dopa

People who are taking Requip 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 Requip 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 at: 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 Requip XL

Keep out of the sight and reach of children.

Do not store above 25°C.

Store in the original package in order to protect from light.

Do not take the tablets after the expiry date which is stated on the carton and blister labels after 'Exp'.

The expiry date refers to the last day of that month.

If the tablet becomes discoloured or shows any sign of deterioration, seek the advice of your pharmacist. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Contents of the pack and other information

What Requip XL contains

The active ingredient in Requip XL is ropinirole hydrochloride.

Each prolonged-release tablet contains 8mg ropinirole (as hydrochloride).

The other ingredients are:

- **tablet core:** hypromellose, hydrogenated castor oil, carmellose sodium, povidone K29-32, maltodextrin, magnesium stearate, lactose monohydrate, silica colloidal anhydrous, mannitol (E421), ferric oxide yellow (E172), glycerol dibehenate, Opadry red O3B25227
- **Opadry red O3B25227 contains:** hypromellose, ferric oxide yellow (E172), titanium dioxide (E171), ferric oxide black (E172), macrogol 400, ferric oxide red (E172)

What Requip XL looks like and contents of the pack

Requip XL are capsule-shaped, red film-coated tablets with 'GS' marked on one side and '5CC' on the other.

Requip XL are available in blister packs of 28 tablets.

Manufactured by: Glaxo Wellcome S.A, Avenida de Extremadura 3, 09400 Aranda de Duero, Burgos, Spain.

Procured from within the EU and repackaged by the Product Licence holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

Requip® XL 8mg prolonged-release tablets; PL 18799/2100

Leaflet date: 11.10.2024

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