

PACKAGE LEAFLET: INFORMATION FOR THE USER

REQUIP® 1MG TABLETS (ropinirole hydrochloride)

Your medicine is available using the name Requip 1mg Tablets, but will be referred to as Requip throughout this leaflet. This medicine is also available in strengths 0.25mg, 2mg and 5mg.

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.**

What is in this leaflet

- What Requip is and what it is used for
- What you need to know before you take Requip
- How to take Requip
- Possible side effects
- How to store Requip
- Contents of the pack and other information

1. What Requip is and what it is used for

Requip is used to treat Parkinson's disease.

The active ingredient in Requip 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.

2. What you need to know before you take Requip

Do not take Requip:

- 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** if you think any of these may apply to you.

Warnings and precautions

Talk to your doctor or pharmacist before taking Requip:

- 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** (such as excessive gambling or excessive sexual behaviour)
- if you have an **intolerance to some sugars** (such as lactose).

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 think any of these may apply to you. Your doctor may decide that Requip isn't suitable for you or that you need extra check-ups while you're taking it.

Children

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

Other medicines and Requip

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 bought without a prescription.

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

These include:

- the **anti-depressant fluvoxamine**
 - HRT** (hormone replacement therapy)
 - the **antibiotics ciprofloxacin or enoxacin**
 - 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**
 - any other **medicine for Parkinson's disease**.
- **Tell your doctor** if you're taking, or have recently taken, any of these.

Remember to tell your doctor if you start taking any other medicine while you're taking Requip.

Requip with food and drink

If you take Requip with food, you may be less likely to feel sick or be sick (vomit). So it's best to take it with food if you can.

Pregnancy and breast-feeding

Requip is not recommended if you are pregnant, unless your doctor advises that the benefit to you taking Requip is greater than the risk to your unborn baby. **Requip 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. Your doctor may advise you to stop taking Requip.

Driving and using machines

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

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 no longer affected.

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

Requip contains lactose monohydrate

Requip tablets contain a small amount of a sugar called lactose monohydrate. If you have an intolerance to lactose or any other sugars, ask your doctor for advice before you take Requip.

Smoking and Requip

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

3. How to take Requip

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 Requip on its own to treat the symptoms of your Parkinson's disease, or you may be given Requip 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 Requip. 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. Your doctor may need to adjust or stop your dose.

How much Requip will you need to take?

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

The usual starting dose is 0.25mg of ropinirole three times each day for the first week. Then your doctor will increase your dose each week, for the next three weeks. After that, your doctor will gradually increase the dose until you are taking the dose that is best for you. The usual is 1mg to 3mg three times each day (making a total daily dose of 3mg to 9mg). If your Parkinson's disease symptoms have not improved enough, your doctor may decide to gradually increase your dose some more.

Some people take up to 8mg of Requip three times a day (24mg daily altogether).

If you are also taking other medicines for Parkinson's disease, your doctor may advise you to gradually reduce the dose of the other medicine.

Don't take any more Requip than your doctor has recommended.

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

Taking your dose of Requip

Take Requip three times a day.

Swallow your Requip tablets whole, with a glass of water. It's best to take Requip with food, because that makes it less likely that you'll feel sick (nauseous).

If you take more Requip than you should Contact a doctor or pharmacist immediately.

If possible, show them the Requip pack.

Someone who has taken an overdose of Requip 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

Do not take a double dose to make up for a forgotten dose. Just take your next dose at the usual time.

If you have missed taking Requip for more than a few days, ask your doctor for advice on how to start taking it again.

If you stop taking Requip

Do not stop taking Requip without advice.

Take Requip for as long as your doctor recommends.

Don't stop unless your doctor advises you to.

If you suddenly stop taking Requip 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 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 everyone gets them. The side effects of Requip 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:

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

- hallucinations (sensing things that are not real)
- being sick (vomiting)
- feeling dizzy (a spinning sensation)
- heartburn
- stomach pain
- 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)
- feeling very sleepy during the day (extreme somnolence)
- falling asleep very suddenly without feeling sleepy first (sudden sleep onset episodes)
- mental problems such as delirium (severe confusion), delusions (unreasonable ideas) or paranoia (unreasonable suspicions)

You may experience the following side effects:

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

Very rare side effects:

may affect **up to 1 in 10,000** people

- changes in liver function, which have shown up in blood tests
- 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

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

- aggression
- excessive use of Requip (craving for large doses of dopaminergic drugs in excess of that required to control motor symptoms, known as dopamine dysregulation syndrome).

If you are taking Requip with L-dopa

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

- uncontrollable movements (dyskinesias) are a very common side effect. 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 Requip

- **Keep this medicine out of the sight and reach of children.**
- The expiry date of these tablets is printed on the label. The expiry date refers to the last day of that month. Do not use the medicine after this date.
- Keep your tablets in their original pack (with this leaflet) in a dry place away from light and at room temperature (at or below 25°C).
- If your doctor tells you to stop taking the tablets, please take them back to the pharmacist for safe disposal. Only keep the tablets if your doctor tells you to.
- If the tablets become discoloured or show signs of deterioration, you should 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 that are no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Requip contains

Your tablets contain the active ingredient ropinirole hydrochloride. Each film-coated tablet contains 1mg ropinirole as the hydrochloride.

The tablets also contain inactive ingredients.

These are lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, magnesium stearate, hypromellose, macrogol 400 and titanium dioxide.

The tablets also contain iron oxide yellow and indigo carmine aluminium as colouring agents.

What Requip looks like and contents of the pack

The tablets are green and pentagonal shaped with 'SB' inscribed on one face and '4892' on the other.

Each pack contains 21 tablets.

Manufacturer

Your medicine is manufactured by:
SmithKline Beecham Pharmaceuticals, Magpie Wood,
Manor Royal, Crawley, Sussex, UK.

Procured from within the EU and repackaged by:
Doncaster Pharmaceuticals Group Ltd., Kirk Sandall,
Doncaster, DN3 1QR.

Product Licence holder: Landmark Pharma Ltd.,
7 Regents Drive, Prudhoe, Northumberland, NE42 6PX.

POM PL No: 21828/0049

Requip® is a registered trademark of the GlaxoSmithKline group of companies.

**Blind or partially sighted?
Is this leaflet hard to see or
read? Call 01302 365000
(Regulatory)**

**Please be ready to give the
following information:**

**Product name:
Requip 1mg Tablets
Reference number:
21828/0049**

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