

Reason for Update: PRAC Recommendation PSUSA/00002661/202207
Market: IE
Agency Approval Date: 05Jun23 (Type IAIN)
Text Date: 18May2023
Issue and Draft No.: Issue 11 Draft 1

REQUIP

Package Leaflet: Information for the User

Requip 0.25 mg film-coated tablets

Requip 1 mg film-coated tablets

Requip 2 mg film-coated tablets

Requip 5 mg film-coated tablets

ropinirole (as hydrochloride)

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

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.

Keep this leaflet. You may need to read it again.

If you have any more questions, ask your doctor or pharmacist (chemist).

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

1. What ReQuip is and what it is used for

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.

Requip 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 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**

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- 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 experience symptoms such as **depression, apathy, anxiety, fatigue, sweating or pain** after stopping or reducing your Requip 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** 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 are taking it.

While you are taking Requip

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.

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.

Requip 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.

Smoking and Requip

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

Other medicines and Requip

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

Some medicines can affect the way Requip works, or make it more likely that you will have side effects.

Requip can also affect the way some other medicines work.

These include:

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

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- **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** if you are taking, or have recently taken, any of these.

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

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

Taking Requip with food and drink

If you take Requip with food, you may be less likely to feel sick (nauseous) 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 of 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.

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 Requip.

Important Information about some of the ingredients in Requip

Requip tablets contain a small amount of 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 Requip.

Requip tablets contain less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium-free".

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).

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

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 0.25 mg 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 dose is 1 mg to 3 mg three times each day (making a total daily dose of 3 mg to 9 mg). 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 8 mg of Requip three times a day (24 mg 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. 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 doses of the medicines you are taking.

Do not take any more Requip than your doctor has recommended.

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

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Taking your dose of Requip

Take Requip three times a day.

Swallow your Requip tablet(s) with a glass of water. It is best to take Requip with food, because that makes it less likely that you will 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 extra tablets or a double dose to make up for a missed dose. Just take your next dose at the usual time.

If you have missed taking Requip for one day or more, 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. Do not 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're worried about side effects, talk to your doctor.

Very common side effects

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

- fainting
- feeling drowsy
- feeling sick (nausea)

Common side effects

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

- hallucinations ('seeing' things that aren't really there)
- being sick (vomiting)
- feeling dizzy (a spinning sensation)
- heartburn
- stomach pain
- swelling of the legs, feet or hands.

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Uncommon side effects

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

- 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)
- 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)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)
- 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).
- Depression, apathy, anxiety, lack of energy, sweating or pain may occur (called dopamine agonist withdrawal syndrome or DAWS) after stopping or reducing your Requip treatment.
- Changes in liver function, which have shown up in blood tests.
- Spontaneous penile erection

You may experience the following side effects:

- 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

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

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. 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 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 HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Requip

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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 label/blister and on the carton. The expiry date refers to the last day of that month.

Do not store above 25 °C. Store in the original package in order to protect from light.

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 to protect the environment.

6. Contents of the pack and other information

What Requip contains

The active substance in Requip is ropinirole.

One film-coated tablet contains 0.25, 1, 2 or 5 mg of ropinirole (as hydrochloride).

The other ingredients are:

- **tablet cores:** lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, magnesium stearate
- **film coats:**

0.25 mg tablet: hypromellose, macrogol 400, titanium dioxide (E171), polysorbate 80 (E433).

1 mg tablet: hypromellose, macrogol 400, titanium dioxide (E171), iron oxide yellow (E172), indigo carmine aluminium (E132).

2 mg tablet: hypromellose, macrogol 400, titanium dioxide (E171), iron oxide yellow (E172), iron oxide red (E172).

5 mg tablet: hypromellose, macrogol 400, titanium dioxide (E171), indigo carmine aluminium (E132), polysorbate 80 (E433).

What Requip looks like and contents of the pack

Requip is provided as pentagonal, film-coated tablets, marked 'SB' on one side.

Requip 0.25 mg: white tablets marked '4890' on reverse side.

Requip 1 mg: green tablets marked '4892' on reverse side.

Requip 2 mg: pink tablets marked '4893' on reverse side.

Requip 5 mg: blue tablets marked '4894' on reverse side.

0.25 mg tablets are supplied in blister packs of 21, 84 or 210 tablets.

1 mg, 2 mg and 5 mg tablets are supplied in blister packs of 21 or 84 tablets.

Not all packs may be available.

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Marketing Authorisation Holder and Manufacturer

The marketing authorisation holder is GlaxoSmithKline (Ireland) Ltd. 12 Riverwalk, Citywest Business Campus, Dublin 24

The manufacturer is Glaxo Wellcome S.A., Avenida de Extremadura 3, 09400 Aranda de Duero, Burgos, Spain

This medicine is authorised in the Member States of the European Economic Area under the following names:

Austria, Belgium, France, Germany, Ireland, Italy, Luxemborug, Malta, The Netherlands, Poland, Spain and Sweden: **Requip**.

This leaflet was last revised in **May 2023**.

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