Package Leaflet: Information for the User

ReQuip
0.25 mg, 1 mg, 2 mg, 5 mg film-coated tablets
ropinirole (as the 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 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

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2 What you need to know before you take ReQuip
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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 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, or aggressive behaviours. 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'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**.

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: **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.

Important Information about some of the ingredients in ReQuip

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

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

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 0.25 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 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.

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, 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)
- 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 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

➔ **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. 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 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

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

Do not store this medicine above 25°C. Keep in a dry place, away 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 protect the environment.

6 Contents of the pack and other information

What ReQuip contains

The active substance in ReQuip is ropinirole (as the hydrochloride) as 0.25 mg, 1 mg, 2 mg or 5 mg tablets.

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 (all strengths) 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.
All strengths are supplied in blister packs**.** 0.25 mg strength carton contain 21 tablets and 1, 2 and 5 mg strength carton contain 84 tablets.

The Marketing Authorisation Holder is SmithKline Beecham Limited, 79 New Oxford Street, London, WC1A 1DG, United Kingdom

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

Other formats

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name	**ReQuip 0.25 mg** **ReQuip 1 mg** **ReQuip 2 mg** **ReQuip 5 mg**
Reference number	10592/0085

This is a service provided by the Royal National Institute of Blind People.

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