1. What Requip-Modutab is and what it is used for

The active ingredient in Requip-Modutab 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-Modutab prolonged-release tablets are 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 dopamine, so it helps to reduce the symptoms of Parkinson's disease.

2. What you need to know before you take Requip-Modutab

Do not take Requip-Modutab:
- 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

Tell your doctor or pharmacist before taking Requip-Modutab:
- 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 condition
- if you have a serious mental health problem
- if you have experienced any unusual urge and/or behaviours (see section 4)
- if you have an intolerance to some sugars (such as lactose)

Tell your doctor if your experience symptoms such as depression, anxiety, lack of energy, sweating or pain after stopping or reducing your Requip-Modutab treatment. If the problems persist make sure to keep this leaflet. If you think that you are developing any unusual symptoms or that the symptoms are getting worse, tell your doctor.

Tell your doctor if you or your family/care notices that you are developing unusual 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-Modutab is not suitable for you, or that you need extra check-ups while you are taking it.

While you are taking Requip-Modutab

Tell your family if you are going to have any unusual symptoms such as an unusual urge to gamble or increased sexual urges. Your doctor may need to adjust your dose.

Other medicines and Requip-Modutab

Tell your doctor or pharmacist if you are taking 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-Modutab.

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

These include:
- the anti-depressant fluvoxamine
- medication for other mental health problems, for example sulpiride
- 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 need additional blood tests if you are taking these medicines with Requip-Modutab:
- Vitamin K antagonists (used to reduce blood clotting) such as Warfarin (coumadin).

Requip-Modutab with food and drink

You can take Requip-Modutab with or without food, as you prefer.

Pregnancy and breast feeding

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

Driving and using machines

Requip-Modutab can make you feel drowsy. It can make people feel extremely sleepy, and it sometimes makes people fall asleep very suddenly without warning. Requip-Modutab can cause hallucinations (seeing, hearing or feeling things that are not there). If affected, do not drive or use machines.

Talk to your doctor if this causes problems for you.

Requip-Modutab 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 Requip-Modutab.

3. How to take Requip-Modutab

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 Requip-Modutab to children. Requip-Modutab is not normally prescribed for people under 18.

You may be given Requip-Modutab on its own to treat the symptoms of your Parkinson’s disease. Or you may be given Requip-Modutab 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-Modutab. Tell your doctor if this happens, as your doctor may need to adjust the doses of the medicines you are taking.

Requip-Modutab tablets are designed to release drug over a 24-hour period. If you have a condition where your medicine passes through your body too quickly, e.g., diarrhoea, the tablet(s) may not dissolve correctly, and it may not work properly. You may see tablet(s) in your stool. If this happens, let your doctor know as soon as possible.

How much Requip-Modutab will you need to take?

It may take a while to find out the correct dose of Requip-Modutab for you.

The recommended starting dose of Requip-Modutab prolonged-release tablets is 2 mg once daily for the first week. Your doctor may increase your dose to 4 mg of Requip-Modutab 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 Requip-Modutab 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.

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

Your doctor will base your dose of Requip-Modutab prolonged-release tablets on the dose of ropinirole film-coated (immediate-release) tablets you were taking.

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

If you take more Requip-Modutab than your doctor has recommended.

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

Taking your dose of Requip-Modutab

Take your Requip-Modutab once a day, at the same time each day.

Swallow your Requip-Modutab 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 have missed taking Requip-Modutab for one day or more

Talk to your doctor or pharmacist if you begin taking a new medicine while you are taking Requip-Modutab:

Remember to tell your doctor or pharmacist if you begin a new medicine while you are taking Requip-Modutab.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone gets them.

The side effects of Requip-Modutab 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 Requip-Modutab:
- feeling drowsy
- feeling sick

Common side effects

These may affect up to 1 in 10 people taking Requip-Modutab:
- feeling drowsy very suddenly without feeling sleepy first (sudden sleep onset episodes)
- being sick (vomiting)
- feeling dizzy (a spinning sensation)
- stomach pain
- constipation
- swelling of the legs, feet or hands.
Uncommon side effects
These may affect up to 1 in 100 people taking Requip-Modutab:
– 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)
– mental problems such as delirium (severe confusion), delusions (unreasonable ideas) or paranoia (unreasonable suspicions)

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).
– changes in liver function, which have shown up in blood tests
– act in an aggressive manner
– excessive use of Requip-Modutab (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 is needed to satisfy your hunger)
– Depression, apathy, anxiety, lack of energy, sweating or pain may occur (called dopamine agonist withdrawal syndrome or DAWSy) after stopping or reducing your Requip-Modutab treatment.

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-Modutab with L-dopa
People who are taking Requip-Modutab 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-Modutab. 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762317. Website: www.hpra.ie;
E-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Requip-Modutab
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 after ‘EXP’. 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 protect the environment.

6. Contents of the pack and other information

What Requip-Modutab contains
The active substance is ropinirole.

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

The other ingredients are:
– Prolonged-release tablet cores: hypromellose 2208, hydrogenated castor oil, carmelllose sodium, povidone 40, maltodextrin, magnesium stearate, lactose monohydrate, silica, colloidal anhydrous, mannitol (E421), iron oxide yellow (E172), glycerol dibehenate
– film coat:
  – hypromellose 2910, iron oxide yellow (E172), titanium dioxide (E171), iron oxide black (E172), macrogol 400, iron oxide red (E172)

What Requip-Modutab looks like and contents of the pack
– Requip-Modutab is provided in the form of red, capsule shaped, prolonged-release tablets, marked ‘GS’ on one side and ‘5CC’ on the other.
– Requip-Modutab comes in blister packs of 84 prolonged-release tablets.

Manufacturer:
SmithKline Beecham Plc., T/A SmithKline Beecham Pharmaceuticals, Manor Royal, Crawley, West Sussex, RH10 9QJ, Great Britain or GlaxoSmithKline Pharmaceuticals S.A. Ul. Gruńwaldzka 189, 60-322 Poznań, Poland or Glaxo Wellcome S.A., Avenida de Extremadura 3, 09400 Aranda de Duero, Burgos, Spain

Product procured from within the EU by the Parallel Product Authorisation Holder: Originalis B.V., Joop Geesinkweg 901, 1114 AB Amsterdam-Duivendrecht, The Netherlands.

Batch Certification Site:
Parallel Product Authorisation Number:
Requip Modutab 8 mg - PPA2306/002/001
Requip-Modutab is a registered trademark of GLAXO GROUP LIMITED

This leaflet was last revised in August 2018.

Blind or partially sighted?
Is this leaflet hard to see or read?
Write to info@originalis.eu to obtain the leaflet in a format suitable for you.