Reason for update: TIB PRAC recommendation (PSUSA/00002661/202507)
Agency Approval Date: 05/08/2026
Text Date: 06/05/2026
Issue and Draft No.: Issue 14 Draft 1

Package leaflet: Information for the user

Requip-Modutab 2 mg prolonged-release tablets

Requip-Modutab 4 mg prolonged-release tablets

Requip-Modutab 8 mg prolonged-release tablets

Ropinirole

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

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 natural 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

Talk to 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 complaint**
- if you have a serious **mental health problem**
- if you have experienced any **unusual urges and/or behaviours** (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-Modutab 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-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 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-Modutab. Your doctor may need to adjust or stop your dose.

Smoking and Requip-Modutab

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

Other medicines and Requip-Modutab

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-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 require 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.

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.

Important Information about some of the ingredients in Requip-Modutab

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.

The 4 mg prolonged-release tablet contains a colouring called **sunset yellow FCF (E110)** which may cause allergic reactions.

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

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 tablet(s) 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 completely and 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 best 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.

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

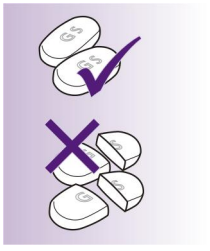
It may take a few weeks for Requip-Modutab to work for you.

Taking your dose of Requip-Modutab

Take 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 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 you should

Contact a doctor or pharmacist immediately. If possible, show them the Requip-Modutab pack.

Someone who has taken an overdose of Requip-Modutab 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-Modutab

Do not take extra prolonged-release tablets or a double dose to make up for a missed dose.

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

If you stop taking Requip-Modutab

Do not stop taking Requip-Modutab without advice.

Take Requip-Modutab for as long as your doctor recommends. Do not stop unless your doctor advises you to.

If you suddenly stop taking Requip-Modutab, 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-Modutab, 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-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:

- fainting
- feeling drowsy
- feeling sick (nausea).

Common side effects

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

- falling asleep very suddenly without feeling sleepy first *(sudden sleep onset episodes)*
- hallucinations ('seeing' things that are not really there)

- being sick (vomiting)
- feeling dizzy (a spinning sensation)
- heartburn
- 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)
- low blood pressure (hypotension)
- feeling very sleepy during the day *(extreme somnolence)*
- 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)
- 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).
- episodes of overactivity, elation or irritability
- depression, apathy, anxiety, lack of energy, sweating or pain may occur (called dopamine agonist withdrawal syndrome or DAWS) after stopping or reducing your Requip-Modutab treatment.
- spontaneous penile erection

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, 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-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. 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-Modutab contains

The active substance in Requip-Modutab is ropinirole.

One prolonged-release tablet contains 2 mg, 4 mg or 8 mg of ropinirole (as hydrochloride).

The other ingredients are:

- **Prolonged-release tablet cores**: hypromellose, hydrogenated castor oil, carmellose sodium, povidone (K29-32), maltodextrin, magnesium stearate, lactose monohydrate, anhydrous colloidal silica, mannitol (E421), iron oxide yellow (E172), glycerol dibehenate
- **film coats**:

  2 mg prolonged-release tablet: OPADRY pink OY-S-24900 (hypromellose, iron oxide yellow (E172), titanium dioxide (E171), macrogol 400, iron oxide red (E172))

  4 mg prolonged-release tablet: OPADRY light brown OY-27207 (hypromellose, titanium dioxide (E171), macrogol 400, sunset yellow FCF aluminium lake (E110), indigo carmine aluminium lake (E132))

  8 mg prolonged-release tablet: OPADRY red 03B25227 (hypromellose, 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 (all strengths) is provided as capsule-shaped, prolonged-release tablets, marked ‘GS’ on one side.

Requip-Modutab 2 mg: pink prolonged-release tablets marked '3V2' on reverse side.

Requip-Modutab 4 mg: light brown prolonged-release tablets marked 'WXG' on reverse side.

Requip-Modutab 8 mg: red prolonged-release tablets marked '5CC' on reverse side.

All strengths: blister packs of 28 or 84 prolonged-release tablets.

Not all packs may be available.

Marketing Authorisation Holder and Manufacturer

The marketing authorisation holder is

GlaxoSmithKline (Ireland) Ltd.

12 Riverwalk,

Citywest Business Campus,

Dublin 24

Ireland

The manufacturer is

Glaxo Wellcome GmbH & Co. KG, Industriestrasse 32-36, 23843, Bad Oldesloe,

Germany or 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, Germany, Ireland, Luxembourg, The Netherlands: **Requip Modutab**

Finland and Sweden: **Requip Depot**

France and Portugal: **Requip LP**

Greece: **Requip XL**

Italy: **Requip**

Spain: **Requip Prolib**

This leaflet was last revised in June 2026.

Trade marks are owned by or licensed to the GSK group of companies.

© 2026 GSK group of companies or its licensor.