PATIENT PACKAGE INSERT IN ACCORDANCE WITH
THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986
The medicine is dispensed according to a physician's prescription only

ReQuip Modutab 2 mg
ReQuip Modutab 4 mg
ReQuip Modutab 8 mg

Film-coated prolonged-release tablets that contain ropinirole (as hydrochloride) 2 mg, 4 mg or 8 mg.
For the list of the inactive and allergenic ingredients in the medicine, see section 2 - “Important information about some of the ingredients in the medicine” and section 6 - “Additional information”.
Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

ReQuip Modutab is indicated for the treatment of Parkinson’s disease under the following conditions:
- Initial treatment as monotherapy, in order to delay the introduction of levodopa.
- In combination with levodopa, over the course of the disease, when the effect of levodopa wears off or becomes inconsistent and fluctuations in the therapeutic effect occur (“end of dose” or **“on-off”** type fluctuations).

The active ingredient in ReQuip Modutab is ropinirole.
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.

You can take ReQuip Modutab either on its own or along with L-dopa (see section 4 of this leaflet for more details).

Therapeutic group: dopamine agonist.

Dopamine agonists affect the brain in a similar way to a natural substance called dopamine.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient ropinirole or to any of the additional ingredients contained in this medicine (listed in section 6).
- You have a **serious kidney disease.**
- You have **liver disease.**

→ **Tell your physician** if you think any of these may apply to you.

Special warnings regarding use of the medicine

Before the treatment with ReQuip Modutab, tell the physician if:

- You are **pregnant** or think you may be pregnant
- You are **breast-feeding**
- You are **under 18 years old**
- You have a **serious heart complaint**
- You have a serious **mental health problem**
- You have experienced any **unusual urges and/or behaviours** (see section 4)
- You have an **intolerance to some sugars** (such as lactose)

Tell your physician if you experience symptoms such as **depression, apathy, anxiety, fatigue, sweating or pain (called dopamine agonist withdrawal syndrome or DAWS)** after stopping or reducing your ReQuip Modutab treatment. If the symptoms persist for more than a few weeks, your physician may need to adjust your dose.

Tell your physician 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 physician may need to adjust or stop your dose.

Tell your physician 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 physician may need to adjust or stop your dose.

→ **Tell your physician** if you think any of these may apply to you. Your physician 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 physician 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 physician may need to adjust or stop your dose.

Smoking

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

Children and adolescents

The medicine is not intended for children and adolescents under the age of 18.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the physician or pharmacist.

Remember to tell your physician 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:

- **fluvoxamine,** an **anti-depressant**
- medication for other **mental health problems**, for example **sulpiride**
- **hormone replacement therapy** (HRT)
- **metoclopramide,** which is used to treat **nausea and heartburn**
- **cimetidine,** used in the **treatment of stomach ulcers**
- the **antibiotics ciprofloxacin** or **enoxacin**
- any other **medicine for the treatment of Parkinson's disease.**

→ **Tell your physician or the pharmacist** if you're taking, or have recently taken, any of these medicines.

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).

Using the medicine and food

You can take ReQuip Modutab with or without food, as you prefer. Because high-fat foods might increase the amount of ropinirole absorbed by your body, it is recommended that you do not take ReQuip Modutab at the same time as a high-fat meal.

Pregnancy and breast-feeding

ReQuip Modutab is not recommended if you are pregnant, unless your physician advises that the benefit of you 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 physician immediately if you are pregnant, if you think you might be pregnant or if you are planning to become pregnant.

Your physician will also advise you if you are breast feeding or planning to do so. Your physician 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 may cause hallucinations (seeing, hearing or feeling things that are not there). If you are affected in this way by the medicine, do not drive or operate machinery.

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 sure you are not affected.

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

Important information about some of the ingredients of the medicine

- ReQuip Modutab tablets contain a sugar called **lactose.** If you have been told by a physician that you have an intolerance to some sugars, contact your physician before taking ReQuip Modutab.
- ReQuip Modutab 4 mg tablets contain a colouring **called sunset yellow** (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 SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the physician's instructions. Check with the physician or pharmacist if you are uncertain about the preparation dosage and treatment regimen.

Do not give ReQuip Modutab to children. ReQuip Modutab is not intended for children and adolescents under the age of 18.

You may be given ReQuip Modutab as a monotherapy to treat the symptoms of your Parkinson's disease, or you may be given ReQuip Modutab together with another medicine called L-dopa (also called *levodopa*).

ReQuip Modutab should be prescribed and your progress monitored by a physician specializing in treatment of Parkinson's disease.

If you are taking L-dopa, you may experience some uncontrollable movements (dyskinesias) when you first start taking ReQuip Modutab. Tell your physician if this happens, as your physician may need to adjust the dose of the medicines you are taking.

Tell your physician 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 physician may need to adjust your dose.

ReQuip Modutab tablets are designed to release drug over a 24hr period. If you have a condition where your medicine passes through your body too quickly, e.g., diarrhoea, the tablets may not dissolve completely and may not work properly. You may see tablets in your stool. If this happens, inform your physician as soon as possible.

How much ReQuip Modutab will you need to take?

It may take a while until the best dose of ReQuip Modutab for you will be found. The dosage and treatment regimen will be determined only by the physician.

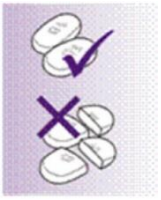
The usual starting dose of ReQuip Modutab tablets is 2 mg once daily for the first week. Your physician may increase your dose to 4 mg of ReQuip Modutab tablets once daily, from the second week of treatment. After that the physician will continue to gradually adjust the medicine dosage until you are taking the best dosage for you. If you are over the age of 65 years, your physician may increase your dosage at a slower rate. Some people take up to 24 mg of ReQuip Modutab tablets each day.

If, at the start of your treatment, you experience side effects that you find difficult to tolerate, speak to your physician.

Do not exceed the recommended dose.

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

Method of administration



Take ReQuip Modutab once a day, at the same time each day. Swallow your ReQuip Modutab tablets whole, with a glass of water. Don't break, halve, chew or crush the tablets - if you do, there's a danger you could overdose, because the medicine will be released into your body too quickly.

ReQuip Modutab tablets are designed to release the drug into your body over a 24-hour period. If the tablets pass through your body in less than 24 hours the medicine may not be completely released. You may see tablets in your stool. If this happens, let your physician know.

If you accidentally have taken a higher dosage you should

Contact a physician 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 took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a physician or to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take this medicine

If you forgot to take ReQuip Modutab at the required time, do not take a double dose. Take the next dose at the usual time and consult the physician.

If you have missed taking ReQuip Modutab for one day or more, ask your physician for advice on how to start taking this medicine again.

Adhere to the treatment regimen recommended by your physician.

Even if your health condition improves, do not stop treatment with the medicine without consulting the physician.

If you stop taking the medicine

Do not stop taking ReQuip Modutab without instructions from the physician. Continue taking ReQuip Modutab for the entire period recommended to you by the physician.

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 physician will reduce your dose gradually.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the physician or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of ReQuip Modutab may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not suffer from any of 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've taken the dose for a while. If you're worried about side effects, talk to your physician.

Very common side effects

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

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

Common side effects

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

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

- 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 severe confusion (delirium), 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
- acting 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 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 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 ReQuip Modutab treatment.

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

If you're 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 physician if this happens, as your physician may need to adjust the dose of the medicines you are taking
- feeling confused is a common side effect

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult with the physician.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

https://sideeffects.health.gov.il/

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Do not store above 25°C. Store in the original package.
- Do not discard medicines in the wastewater or household waste bin. Ask the pharmacist how to dispose of medicines that are no longer in use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

- In addition to the active ingredients, the medicine also contains:

tablet cores:

Hypromellose 2208, glycerol dibehenate, mannitol (E421), lactose monohydrate, povidone K29-32, carmellose sodium, hydrogenated castor oil, maltodextrin, magnesium stearate, anhydrous colloidal silica and ferric oxide yellow (E172).

film coats:

2 mg tablet:

Hypromellose 2910, titanium dioxide (E171), macrogol 400, ferric oxide red (E172), ferric oxide yellow (E172).

4 mg tablet:

Hypromellose 2910, titanium dioxide (E171), macrogol 400, sunset yellow (E110), indigo carmine (E132).

8 mg tablet:

Hypromellose 2910, titanium dioxide (E171), macrogol 400, ferric oxide red (E172), ferric oxide black (E172), ferric oxide yellow (E172).

Also see section 2 in this leaflet – "Important information about some of the ingredients in the medicine".

• What the medicine looks like and the contents of the package:

ReQuip Modutab prolonged-release tablets (all strengths) are provided as capsule-shaped, film-coated tablets, marked 'GS' on one side.

ReQuip Modutab 2 mg: pink tablets marked '3V2' on reverse side.

ReQuip Modutab 4 mg: light brown tablets marked 'WXG' on reverse side.

ReQuip Modutab 8 mg: red tablets marked '5CC' on reverse side.

All strengths: blister packs, 28 or 84 tablets.

Not all package sizes may be marketed.

• License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.

• Manufacturer: Glaxo Wellcome S.A., Burgos, Spain.

• Registration number of the medicine in the National Drug Registry of the Ministry of Health:

ReQuip Modutab 2 mg: 141-62-31838

ReQuip Modutab 4 mg: 141-64-31839

ReQuip Modutab 8 mg: 141-63-31840

Revised in February 2022 according to MoH guidelines.

Req MT PT V8B