

REQUIP PD 24 HOUR[®] PROLONGED RELEASE TABLET

Ropinirole hydrochloride (2 mg, 4 mg, 8 mg)

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What REQUIP PD is used for

REQUIP PD is used to treat Parkinson's disease.

How REQUIP PD works

The active ingredient in REQUIP PD 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 brain. Ropinirole has effects similar to those of natural dopamine, so it helps to reduce the symptoms of Parkinson's disease.

Before you use REQUIP PD

- When you must not use it

Don't take REQUIP PD if you are allergic (hypersensitive) to ropinirole or any of the other ingredients of REQUIP PD. If you think this applies to you, don't take REQUIP PD until you have checked with your doctor.

- Before you start to use it

Before you take REQUIP PD your doctor needs to know:

- If you're under 18
- If you have heart disease
- If you have liver disease
- If you have kidney disease
- If you have a serious mental health problem

- If you have experienced any unusual urges or behaviours (such as excessive gambling or excessive sexual behaviour)
- If you have an intolerance to some sugars (such as lactose)

Check with your doctor if you think any of these may apply to you. Your doctor will decide whether REQUIP PD is suitable for you.

REQUIP PD is not usually recommended for use during pregnancy. If you are pregnant or think you could be, or if you are planning to become pregnant don't take REQUIP PD without checking with your doctor. Your doctor will weigh up the benefit to you and risk to your baby of taking REQUIP PD while you're pregnant. Breast-feeding is not recommended during treatment with REQUIP PD as it may affect your milk production. Talk to your doctor about this.

- Taking other medicines

Tell your doctor or pharmacist if you're taking any other medicines, if you've taken any recently, or if you start taking new ones. This includes medicines you bought without a prescription.

Some medicines can affect how REQUIP PD works. These include medicines known to have the opposite effect to REQUIP PD such as:

- Metoclopramide (used to treat nausea and heartburn)
 - Any medicine used to treat schizophrenia such as sulpiride
- Tell your doctor or pharmacist if you are taking any of these. Your doctor or pharmacist will decide if you should take REQUIP PD with these medicines.

Your doctor may decide to adjust your dose of REQUIP PD if you start or stop taking any of the following:

- Fluvoxamine (used to treat depression)
 - Some antibiotics (used to treat infections) such as ciprofloxacin or enoxacin
 - HRT (hormone replacement therapy) used during the menopause
- Tell your doctor or pharmacist if you are taking any of these.

How to use REQUIP PD

- How much to use

The usual starting dose of REQUIP PD is one 2 mg tablet once a day. Your doctor may gradually increase your dose until your symptoms are controlled. The usual maximum daily dose is 24 mg taken once a day. It may take a while to find the best dose of REQUIP PD for you. Always take the dose that your doctor recommends.

If you have severe kidney disease your doctor will decide if REQUIP PD is suitable for you. You may need to take a lower dose.

REQUIP PD tablet(s) 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 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.

- When to use it

It is best to take your tablet(s) at the same time each day. You can take REQUIP PD with or without food. Swallow your REQUIP PD tablet(s) whole with some water. Don't chew, crush or split the tablet(s) – if you do, there's a danger you could overdose, because the medicine may be released into your body too quickly.

- How long to use it

Take REQUIP PD for as long as your doctor recommends. Don't stop unless your doctor advises you to. If you suddenly stop taking REQUIP PD, your Parkinson's disease symptoms may quickly get much worse.

If you need to stop taking REQUIP PD, your doctor will reduce your dose gradually. Ask your doctor or pharmacist if you have any questions on the use of this product.

- If you forget to use it

If you have missed your dose for one day or more, ask your doctor for advice on how to start taking it again. Don't take extra tablets to make up for a missed dose.

- If you use too much (overdose)

If you take too many tablets of REQUIP PD you may be more likely to have side effects. Contact your doctor or pharmacist for advice. If possible, show them the REQUIP PD pack.

While you are using it

- Things you must do

Always take REQUIP PD exactly as your doctor has told you to. Check with your doctor or pharmacist if you're not sure.

- Things you must not do

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

- Things to be careful of

Unusual urges or behaviours

Tell your doctor if you or your family/caregiver notices that you are behaving in a way that is unusual for you. Examples of this are an unusual urge to gamble, increased sexual urges or behaviours or an uncontrollable urge to shop or eat while you are taking REQUIP PD.

REQUIP PD and L-dopa

When treating Parkinson's disease, REQUIP PD can be taken on its own,

or with another medicine called L-dopa (also called levodopa). If you are taking L-dopa you may experience some uncontrolled jerky movements when you first start taking REQUIP PD. Tell your doctor if this happens, as your dose of L-dopa may need to be reduced.

Smoking and REQUIP PD

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

Alcohol and REQUIP PD

Because REQUIP PD and alcohol can make you feel sleepy, drinking alcohol while you're taking REQUIP PD is not recommended.

Driving and using machines

REQUIP PD can make you feel drowsy or sleepy. It may also make you feel dizzy, or experience a spinning sensation (*vertigo*) when you start taking it. On very rare occasions falling asleep suddenly without any warning of sleepiness has occurred (*see side effects*). You need to take your safety and that of others into account if you drive or use machines that could cause injury. Don't drive or use machines if you get these side effects.

Side Effects

Like all medicines, REQUIP PD can cause side effects, but not everyone gets them. The more common side effects of REQUIP PD are more likely to happen when you first start taking it, or when your dose has just been increased. They usually become less troublesome after you've taken the dose for a while. If you're worried about side effects, talk to your doctor.

Look out for important changes in your behaviour

Some people taking REQUIP PD have experienced unusual urges or behaviours. Tell your doctor if you or your family/caregiver notices that you are behaving in a way that is unusual for you such as:

- An unusual urge to gamble

- Increased sexual urges or behaviours
- Uncontrollable urge to shop
- Uncontrollable urge to eat

Tell your doctor as soon as possible if you notice any of these changes in your behaviour. Your doctor may need to adjust or stop your dose.

Very common side effects

These may affect up to 1 in 10 people ($\geq 1/10$):

- Feeling drowsy
- Feeling sick (*nausea*)
- Fainting

When REQUIP PD is taken with L-dopa:

- Uncontrolled jerky movements (*dyskinesia*) may occur when you first start taking REQUIP PD. Tell your doctor if this happens as the dose of your medicines may need adjusting.

Common side effects

These may affect between 1 in 100 to 1 in 10 people ($\geq 1/100$, $< 1/10$):

- Hallucination (seeing or hearing things that aren't really there)
- Feeling dizzy (a spinning sensation)
- Swelling of the legs, feet or hands
- Constipation
- A drop in blood pressure that may make you feel dizzy or faint especially when standing up from a sitting or lying position
- Being sick (vomiting)
- Acid indigestion (heartburn)
- Stomach ache

Uncommon side effects

These may affect between 1 in 1000 to 1 in 100 people ($\geq 1/1000$, $< 1/100$):

- Mental health problems such as severe confusion (*delirium*), irrational ideas (*delusions*) or irrational suspicions (*paranoia*)
- Developing unusual urges or behaviours (such as excessive gambling, excessive sexual behaviour or an uncontrollable urge to shop or eat)
- Acting in an aggressive manner

Very rare side effects

These may affect less than 1 in 10,000 people (<1/10000):

- Falling asleep suddenly without any warning of sleepiness
- Feeling extremely tired during the day
- 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 itching.

Tell your doctor or pharmacist if any of the side effects listed become severe or troublesome, or if you notice any side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

Storage and Disposal of REQUIP PD

- *Storage*

Keep out of the reach and sight of children. Do not take REQUIP PD after the expiry date shown on the pack.

Do not store above 25°C. Store in the original package.

- *Disposal*

If you have any unwanted REQUIP PD tablets, don't dispose of them in your waste water or household rubbish. Ask your pharmacist how to dispose of medicines no longer required. This will help to protect the environment.

Product Description

- *What it looks like*

Film-coated, capsule-shaped tablets for oral administration. The tablet strengths are distinguished by colour and debossing;

- 2 mg: pink, capsule-shaped, film-coated tablets marked "GS" on one side and "3V2" on the other.
- 4 mg: light brown, capsule-shaped, film-coated tablets marked "GS" on one side and "WXG" on the other.
- 8 mg: red, capsule-shaped, film-coated tablets marked "GS" on one side and "5CC" on the other.

- *Ingredients*

- Active ingredient(s)
Ropinirole hydrochloride equivalent to 2, 4 or 8 mg ropinirole free base.

- Inactive ingredient(s)

Requip PD 24 Hours 2mg Prolonged Release Tablets

Lactose monohydrate, Silica colloidal anhydrous, hypromellose 2208, yellow ferric oxide (E 172, CI 77492), Mannitol, Glycerol dibehenate, povidone K29-32, MALTODEXTRIN, Opadryl Pink OY-S-24900, castor oil (hydrogenated), magnesium stearate, carmellose sodium

Requip PD 24 Hours 4mg Prolonged Release Tablets

Lactose monohydrate, Silica colloidal anhydrous, hypromellose 2208, yellow ferric oxide (E 172, CI 77492), Mannitol, Glycerol dibehenate, povidone K29-32, MALTODEXTRIN, Opadry Tan OY-27207, castor oil (hydrogenated), magnesium stearate, carmellose sodium

Requip PD 24 Hours 8mg Prolonged Release Tablets

Lactose monohydrate, Silica colloidal anhydrous, hypromellose 2208, Yellow ferric oxide (E 172, CI 77492), Mannitol, Glycerol Dibehenate, Povidone K29-32, MALTODEXTRIN, Opadry Red 03B25227, Castor oil (hydrogenated), Magnesium Stearate, Carmellose Sodium

- *MAL number*

Requip PD 24 Hour 2mg Prolonged Release Tablet
MAL10053654AZ

Requip PD 24 Hour 4mg Prolonged Release Tablet
MAL10053656AZ

Requip PD 24 Hour 8mg Prolonged Release Tablet
MAL10053659AZ

Manufacturer

Requip PD Tablets 2mg, 4mg and 8mg
Glaxo Wellcome S.A., Avenida De Extremadura 3, Aranda de Duero, Burgos, Spain

Product Registration Holder

GlaxoSmithKline Pharmaceutical Sdn. Bhd.
Level 6, Quill 9,
112 Jalan Semangat,
46300 Petaling Jaya,
Selangor, Malaysia

Date of Revision

20 Jun 2016

Serial Number:

BPFK(R4/1)170616/00133

