

# REQUIP<sup>®</sup> TABLET

Ropinirole hydrochloride (0.25mg, 1mg)

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## What REQUIP is used for

REQUIP is used to treat Parkinson's disease and restless legs syndrome (RLS).

## How REQUIP works

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 part of their brain. Ropinirole has effects similar to those of natural dopamine, so it helps to reduce the symptoms of Parkinson's disease.

Restless legs syndrome is also called Ekbom syndrome. People with restless legs syndrome have an irresistible urge to move their legs, and sometimes their arms and other parts of their body. They can often have unpleasant sensations in their limbs — sometimes described as 'crawling' or 'bubbling' — which can begin as soon as they sit or lie down, and which are only relieved by movement. This can often cause problems with sitting still, and especially with sleeping.

REQUIP relieves the unpleasant sensations, and so reduces the urge to move the legs and other limbs. This can help you sleep better at night.

## Before you use REQUIP

### - When you must not use it

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

### - Before you start to use it

Before you take REQUIP 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 is suitable for you.

REQUIP 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 without checking with your doctor. Your doctor will weigh up the benefit to you and risk to your baby of taking REQUIP while you're pregnant. Breast-feeding is not recommended during treatment with REQUIP 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 works. These include medicines known to have the opposite effect to REQUIP 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 with these medicines.

Your doctor may decide to adjust your dose of REQUIP 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

### - How much to use

#### *Parkinson's disease*

Take REQUIP three times a day. The usual starting dose of REQUIP is one 0.25 mg tablet three times a day. Your doctor may gradually increase your dose until your symptoms are controlled. It may take a while to find the best dose of REQUIP for you. Always take the dose that your doctor recommends.

#### *Restless Legs Syndrome*

The usual starting dose of REQUIP is one 0.25 mg tablet once a day. Your doctor may gradually increase your dose until your symptoms are controlled. The usual maximum dose is 4 mg once a day. It may take a while to find the best dose of REQUIP for you. Always take the dose that your doctor recommends.

If you have severe kidney disease your doctor will decide if REQUIP is

suitable for you. You may need to take a lower dose.

- When to use it

It is best to take your tablet(s) at the same time each day. You can take REQUIP with or without food.

*Restless Legs Syndrome*

REQUIP is usually taken just before bedtime, but you can take it up to three hours before going to bed.

- How long to use it

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.

If you need to stop taking REQUIP, 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 you may be more likely to have side effects. Contact your doctor or pharmacist for advice. If possible, show them the REQUIP pack.

**While you are using it**

- Things you must do

Always take REQUIP 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.

*REQUIP and L-dopa*

When treating Parkinson's disease, REQUIP 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. Tell your doctor if this happens, as your dose of L-dopa may need to be reduced.

*Smoking and REQUIP*

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

*Alcohol and REQUIP*

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

*Driving and using machines*

REQUIP 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 can cause side effects, but not everyone gets them. The more common side effects of REQUIP 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 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.

Some people taking REQUIP find that their RLS symptoms get worse, for example they may:

- Start earlier than usual or be more intense
  - Affect other parts of the body, such as the arms
  - Return in the early morning
- Tell your doctor as soon as possible if you get any of these symptoms.

Very common side effects

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

*Parkinson's Disease*

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

When REQUIP is taken with L-dopa:

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

*Restless Legs Syndrome*

- Being sick (vomiting)
- Feeling sick (*nausea*)

Common side effects

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

*Parkinson's Disease*

- Hallucinations (seeing or hearing things that aren't really there)
- Feeling dizzy (a spinning sensation)
- Stomach ache
- Being sick (vomiting)

- Acid digestion (heartburn)
- Swelling of the legs, feet or hands
- A drop in blood pressure that may make you feel dizzy or faint especially when standing up from a sitting or lying position
- Constipation

When REQUIP is taken with L-dopa:

- Confusion

#### *Restless Legs Syndrome*

- Feeling dizzy (a spinning sensation)
- Feeling drowsy
- Fainting
- Stomach ache
- Tiredness (fatigue)
- A drop in blood pressure that may make you feel dizzy or faint especially when standing up from a sitting or lying position
- Worsening of RLS (symptoms may start earlier than usual or be more intense, or affect other parts of the body, such as the arms or return in the early morning)

#### Uncommon side effects

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

#### *Parkinson's Disease and Restless Legs Syndrome*

- 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 ( $< 1/10000$ ):

#### *Parkinson's Disease and Restless Legs Syndrome*

- 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](http://portal.bpfk.gov.my) (Consumers → Reporting)

#### **Storage and Disposal of REQUIP**

##### - Storage

Keep out of the reach and sight of children. Do not take REQUIP 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 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, pentagonal-shaped tablets for oral administration. The tablet strengths are distinguished by colour and debossing;

0.25 mg: white, pentagonal-shaped, film-coated tablets marked "SB" on one side and "4890" on the other.

1.0 mg: green, pentagonal shaped, film-coated tablets marked "SB" on one side and "4892" on the other.

##### - Ingredients

- Active ingredient(s)

Ropinirole hydrochloride equivalent to 0.25 or 1.0 mg ropinirole free base.

- Inactive ingredient(s)

##### *Tablet cores:*

lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, magnesium stearate.

##### *Film coats:*

0.25 mg: hydroxypropylmethyl cellulose, polyethylene glycol 400, titanium dioxide

1.0 mg: hydroxypropylmethyl cellulose, polyethylene glycol 400, titanium dioxide, iron oxide yellow, indigo carmine aluminium lake E132 (FD&C Blue No.2)

##### - MAL number

REQUIP Tablet 0.25mg  
MAL19990966AZ

REQUIP Tablet 1mg  
MAL19990967AZ

#### **Manufacturer**

Glaxo Wellcome S.A.  
Aranda de Duero, Spain

#### **Product Registration Holder**

GlaxoSmithKline Pharmaceutical Sdn. Bhd.  
Level 6, Quill 9,  
112 Jalan Semangar,  
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#### **Date of Revision**

20 Jun 2016

#### **Serial Number:**

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