

PACKAGE LEAFLET: INFORMATION FOR THE USER

Ropinirole Glenmark 5 mg film-coated tablets

Ropinirole

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- 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.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

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

1. WHAT ROPINIROLE GLENMARK IS AND WHAT IT IS USED FOR

ROPINIROLE GLENMARK belongs to a group of medicines called dopamine agonists. Dopamine agonists act like a naturally occurring chemical in your brain called dopamine.

ROPINIROLE GLENMARK is used to treat Parkinson's disease. The cause of Parkinson's disease is a lack of the substance dopamine in the brain. ROPINIROLE GLENMARK may be used alone or in combination with other medicines against Parkinson's disease to achieve a more effective treatment.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ROPINIROLE GLENMARK

Do not take ROPINIROLE GLENMARK

- if you are allergic (hypersensitive) to the active ingredient, ropinirole, or any of the other ingredients of ROPINIROLE GLENMARK (see sections 4 and 6).
- if you have serious liver disease
- if you have serious kidney disease

If you are unsure, it is essential that you talk to your doctor.

Warnings and precautions

Talk to your doctor before taking Ropinirole Glenmark if you:

- are pregnant or think you may be pregnant
- are breast-feeding
- are under 18 years old
- have liver disease
- have a serious heart complaint. (Your doctor may want to monitor your blood pressure, especially when you first start taking ropinirole)
- have a serious mental health problem
- have experienced any unusual urges and / or behaviours (such as excessive gambling or excessive sexual behaviour)
- have an intolerance to some sugars (such as lactose)

Talk to your doctor if you think any of these may apply to you. If you and your doctor decide that you can take ropinirole, your doctor will probably ask you to have extra check-ups while you are taking it.

Take special care with Ropinirole Glenmark

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 or 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.

Other medicines and ropinirole

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines can affect the way ropinirole works, or make it more likely that you will have side effects. Ropinirole can also affect how some other medicines work. These medicines include:

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

Talk to your doctor if you think any of these may apply to you. If you and your doctor decide that you can take this medicine, your doctor will probably ask you to have extra check-ups while you are taking it.

Remember to tell your doctor if you start taking any other medicine while taking this medicine.

Taking ROPINIROLE GLENMARK with food and drink

If you take ropinirole with food, you may be less likely to feel sick (nauseous) or be sick (vomit). So it may be best to take it with food if you can.

No information is available on alcohol consumption while taking ropinirole and it should therefore be avoided.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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

ROPINIROLE GLENMARK 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 ROPINIROLE GLENMARK.

Driving and using machines

ROPINIROLE GLENMARK may have an influence on the ability to drive and use machines as it may possibly cause dizziness or a spinning sensation.

Also ROPINIROLE GLENMARK can cause extreme sleepiness (somnolence) and sudden sleep onset episodes. If you do suffer from these effects you must not drive or put yourself in a situation where sleepiness or falling asleep may put you at risk of serious injury or death (for example using machinery) until you are no longer affected.

ROPINIROLE GLENMARK contains lactose

This medicinal product contains lactose. If you have an intolerance to lactose or any other sugars, ask your doctor for advice before you take this medicine.

3. HOW TO TAKE ROPINIROLE GLENMARK

Always take ROPINIROLE GLENMARK exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The starting dose is 0.25 mg ropinirole three times per day for one week. Then the dose is gradually increased in accordance with the following:

- 1st week: 0.25 mg ropinirole 3 times daily
- 2nd week: 0.5 mg ropinirole 3 times daily
- 3rd week: 0.75 mg ropinirole 3 times daily
- 4th week: 1.0 mg ropinirole 3 times daily

Hereafter your doctor may increase or decrease the dose that you are taking to get the best effect. The usual dose is between 1 mg to 3 mg ropinirole taken three times daily (a total daily dose of 3 mg to 9 mg), but if sufficient effects are not achieved or maintained, the total daily dose may be gradually increased up to 24 mg.

ROPINIROLE GLENMARK may also be used in combination with other medicines for Parkinson's disease. If you are using other medicines for Parkinson's disease your doctor may eventually reduce its dose when you use ROPINIROLE GLENMARK.

Method of administration

Take ropinirole three times a day.

Swallow the ROPINIROLE GLENMARK tablet(s) whole with a glass of water. Do not chew or crush the tablet(s).

You can take ROPINIROLE GLENMARK with or without food. If you take ROPINIROLE GLENMARK with food you may be less likely to feel sick (nauseous).

Use in children and adolescents

ROPINIROLE GLENMARK is not normally prescribed in children and adolescents under 18 years of age.

If you take more ROPINIROLE GLENMARK than you should

Someone who has taken an overdose may have any of these symptoms: feeling sick (nausea) or being sick (vomiting), dizziness (a spinning sensation), feeling drowsy, mental or physical tiredness, stomach pain, fainting and hallucinations.

If you take more ROPINIROLE GLENMARK than you should or if someone else has taken your medicine, tell a doctor or pharmacist immediately. Show them the package.

G GLENMARK GENERICS LTD.	DATE: 24.4.'13	PANTONE SHADE NO: 1 (Black)
PRODUCT NAME: Ropinirole 5 mg (Insert-front)	PKG. DEV.:	Item code, Version, Consistency of Design, overprint area, Pack size, Dimensions & Layout
ITEM CODE: XXX _____ VERSION: XXXXX	RA	Regulatory Text
LOCATION: Goa	QA:	Entire Text
JAR SIZE: _____	REMARKS:	
PACK SIZE: _____		
ACTUAL SIZE: 170 x 360 mm		
SPECIFICATION: 170 x 30 mm		
40 gsm Bible Paper		

If you forget to take ROPINIROLE GLENMARK

Do not take a double dose to make up for a forgotten dose. When you do remember to take ROPINIROLE GLENMARK, take your next dose of ROPINIROLE GLENMARK at the usual time.

If you have missed taking ROPINIROLE GLENMARK for more than a few days consult your doctor for advice on how to start taking ROPINIROLE GLENMARK again.

If you stop taking ROPINIROLE GLENMARK

Ropinirole may take a few weeks to work for you. Take ropinirole for as long as your doctor recommends. Don't stop unless your doctor advises you to.

If you suddenly stop taking ropinirole your symptoms may quickly get much worse.

If you need to stop taking ropinirole your doctor will reduce your dose gradually.

If your symptoms worsen after you stop treatment with ROPINIROLE GLENMARK, you should contact your doctor.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

The side effects of ropinirole 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.

STOP taking Ropinirole and seek immediate medical attention if you experience any of the following symptoms of a severe allergic reaction:

- swelling of the face, lips, tongue or throat
- difficulty in swallowing
- difficulty breathing or wheezing
- itchy skin or nettle rash (hives)
- dizziness

You may experience the following side effects:

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 normal and more than is needed to satisfy your hunger).

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

Very common: may affect more than 1 in 10 people

- feeling sick (nausea)
- feeling drowsy
- fainting

Common: may affect up to 1 in 10 people

- fainting, feeling faint or dizzy especially when standing up.
- hallucinations (sensing things that are not real)
- feeling confused
- feeling dizzy (a spinning sensation)
- being sick (vomiting), heartburn, stomach ache or upset stomach (with indigestion or bloating), abdominal pain
- swelling of the legs

Uncommon: 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)
- feeling very sleepy during the day (extreme somnolence)
- falling asleep very suddenly without feeling sleepy first (sudden sleep onset episodes)
- mental problems such as delirium (severe confusion), delusions (unreasonable ideas) or paranoia (unreasonable suspicions)

Some people taking ropinirole have had a compulsive urge to gamble or increased sexual urges and/or behaviours

Not known (cannot be estimated from the available data)

- changes in liver function, which have shown up in blood tests.
- 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.

If you are taking ropinirole with L-dopa

People who are taking ropinirole with L-dopa may develop other side effects over time:

- Uncontrollable movements (dyskinesias) are a very common side effect. 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

If you get any side effects talk to your doctor or pharmacist as soon as possible. This includes any side effects not listed in this leaflet.

5. HOW TO STORE ROPINIROLE GLENMARK

Keep this medicine out of the sight and reach of children.

Do not use ROPINIROLE GLENMARK after the expiry date which is stated on the blister/bottle and the outer carton after Exp. The expiry date refers to the last day of that month.

Do not store above 30°C.

Blisters:

Store in the original package in order to protect from moisture.

Bottles:

Keep the bottle tightly closed in order to protect from moisture.

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 ROPINIROLE GLENMARK contains

- The active substance is ropinirole. Each film-coated tablet contains ropinirole hydrochloride equivalent to 5.0 mg of ropinirole.

The other ingredients are:

Tablet Cores

Lactose, Anhydrous
Lactose Monohydrate
Cellulose, microcrystalline (E460)
Citric acid, anhydrous (E330)
Croscarmellose sodium (E468)
Magnesium Stearate (E572)

Film Coating

5.0 mg	Hypromellose (E464), Titanium dioxide (E171), Macrogol 400, Talc, Indigo carmine aluminium lake (E132), Brilliant blue FCF Aluminium lake (E133)
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What ROPINIROLE GLENMARK looks like and contents of the pack

Film-coated tablet.

5.0 mg Blue, circular, bevelled edged, biconvex film coated tablets with '259' debossed on one side and 'G' on the other side.

The tablets are packed in either plain Aluminium/Aluminium blisters, white, opaque Triplex(PVC/PE/Aclar)/Aluminium blisters or white opaque HDPE bottles with polypropylene child-resistant closure

Pack Sizes

Blister: 21 and 84

Bottle: 84

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Glenmark Generics (Europe) Ltd,
Laxmi House, 2-B Draycott Avenue,
Kenton, Harrow, Middlesex HA3 0BU
United Kingdom.

Manufacturer

Glenmark Pharmaceuticals s.r.o Hvězdova 1716/2b, 140 78 Praha 4, Czech Republic
Glenmark Generics (Europe) Limited, The Old Sawmill, Hatfield Park, Hatfield, Hertfordshire, AL9 5PG, United Kingdom

This medicinal product is authorised in the Member States of the EEA under the following names:

The Netherlands	Ropinirol Glenmark Filmomhulde Tabletten
Denmark	Ropinirol EQL Pharma
Germany	Ropinirol Glenmark Filmtabletten
Ireland	Ropinirole Glenmark film-coated tablets
UK	Ropinirole film-coated tablets

This leaflet was last revised in 02/2013.

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