

PACKAGE LEAFLET: INFORMATION FOR THE USER
Ropinirole Glenmark 0.25, 0.5, 1, and 2 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.

Ropinirole Glenmark is also used to treat the symptoms of moderate to severe idiopathic Restless Legs Syndrome (RLS), a condition characterised by an irresistible urge to move the legs and occasionally the arms, usually accompanied by uncomfortable sensations such as tingling, burning or prickling. These feelings occur during periods of rest or inactivity such as sitting or lying down, especially in bed, and are worse in the evening or at night. Usually the only relief is obtained by walking about or moving the affected limbs, which often leads to problems sleeping. Ropinirole Glenmark relieves the discomfort and reduces the urge to move the limbs that disrupt night time sleep.

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 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 doctor may need to adjust or stop your dose.

If during treatment of Restless Legs Syndrome, your symptoms become much worse, start earlier in the day or after less time at rest or affect other parts of your body such as your arms, you should contact your doctor who may adjust the dose of ROPINIROLE GLENMARK that you are taking.

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 sulpride.
- any other drug, which blocks dopamine in the brain.
- metoclopramide, which is used to treat nausea and heartburn.
- cimetidine, used in 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 ropinirole, 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 ropinirole.

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 (somnia) 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.

ROPINIROLE GLENMARK is used differently depending on the disease.

Parkinson's disease

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 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.

Restless Legs Syndrome

Take ROPINIROLE GLENMARK once a day, every day at the same time. ROPINIROLE GLENMARK is usually taken just before bedtime, but can be taken up to 3 hours before going to bed. The exact dose of ROPINIROLE GLENMARK people take can be different. Your doctor will decide on the dose you need to take each day and you should follow the doctor's instructions. When you first start taking ROPINIROLE GLENMARK, the dose you take will be increased gradually.

The starting dose is 0.25 mg once daily. After two days your doctor will probably increase your dose to 0.5 mg once daily for the remainder of your first week of treatment. Then your doctor may gradually increase your dose over the next three weeks up to a dose of 2 mg per day.

If a 2 mg daily dose does not improve your RLS symptoms enough, your doctor may gradually increase your dose some more, up to a maximum of 4 mg daily. After you have been taking ropinirole for three months, your doctor may adjust your dose or advise you to stop taking it.

If you feel that the effects of this medicine are too strong or too weak, talk to your doctor or your pharmacist. Do not take more ropinirole than your doctor has recommended.

Carry on taking this medicine as your doctor advises, even if you do not feel better. Ropinirole may take a few weeks to work for you.

Method of administration

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.

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.

Parkinson's disease: If you have missed taking ROPINIROLE GLENMARK for one or more day consult your doctor for advice on how to start taking ROPINIROLE GLENMARK again.

Restless Legs Syndrome: 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.

GLENMARK GENERICS LTD.		DATE: 24.4.'13	PANTONE SHADE NO: 1 (Black)
PRODUCT NAME: Ropinirole 0.25-2mg Insr-front	PKG. DEV.:	Item code, Version, Consistency of Design, overprint area, Pack size, Dimensions & Layout	
ITEM CODE: <u> XXX </u> VERSION: <u> XXXX </u>	RA	Regulatory Text	
LOCATION: <u> Goa </u>	QA:	Entire Text	
JAR SIZE: _____	REMARKS:		
PACK SIZE: _____			
ACTUAL SIZE: 170 x 480 mm			
SPECIFICATION: 170 x 40 mm			
40 gsm Bible Paper			

