

ROPIN



Ropinirole hydrochloride 0.25, 0.5, 1, 2, & 5 mg tablets

What Is In This Leaflet

This leaflet answers some common questions about ROPIN tablets. It does not contain all the information available on this medicine. It does not take the place of consulting with your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ROPIN against the benefits they expect it will have for you. If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with your medicine as you may need to read it again.

What ROPIN is used for and how it works

ROPIN is used to treat Parkinson's Disease.

Parkinson's Disease is a disease of the nervous system associated with trembling of the arms and legs, stiffness and rigidity of the muscles and slowness of movement. It is caused by the progressive loss of brain cells, which produce the chemical dopamine. As the cells die, less dopamine is produced for the area of the brain that controls movement. Symptoms develop as the brain cells die off and dopamine levels decrease.

ROPIN belongs to a group of medicines known as dopamine agonists. Dopamine agonists work by increasing the dopamine levels in the brain. This helps to lessen the symptoms of Parkinson's Disease.

You may be given ROPIN on its own. It may also be given with another drug used to treat Parkinson's Disease (Levodopa/L-Dopa) to improve control of your symptoms.

Before you take ROPIN

When you must not take it

Do not take ROPIN if you are allergic to medicines containing ropinirole or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include hayfever, skin rash, itching or hives.

Do not take ROPIN if you have any of the following medical conditions:

- Severe liver disease
- Severe kidney disease
- Serious psychiatric disorder.

If you are not sure whether any of these apply to you, check with your doctor.

Do not take ROPIN if you are pregnant. ROPIN may affect your unborn baby if you take it during pregnancy.

Do not take this medicine if you are breastfeeding.

Do not take ROPIN if the expiry date printed on the pack has passed or the packaging shows signs of tampering.

Do not give ROPIN to children. Safety and effectiveness in children has not been established.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you take it

Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor or pharmacist if you have or have had any of the following health conditions:

- Heart problems
- Severe mental condition
- History of any unusual urges and/or behaviours (such as excessive gambling or excessive sexual behaviour).

Tell your doctor or pharmacist if you smoke, start smoking or give up smoking while taking ROPIN. The dose may need adjustment.

If you have not told your doctor about any of the above, tell them before you start taking ROPIN.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any you get without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may be affected by the way other medicines work.

Some of the medicines that may interfere with ROPIN include:

- Medicines to treat psychiatric conditions
- Some antibiotics e.g. ciprofloxacin
- Metoclopramide, a medicine usually taken for digestive disorders
- Hormone replacement therapy
- Other medicines for Parkinson's Disease.

These medicines may be affected by ROPIN or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take ROPIN

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How much to take

When you first start taking ROPIN, the amount you take will be increased gradually. Your doctor may then increase or decrease the amount of ROPIN that you are taking to get the best effect.

The usual adult maintenance dose is between 1 mg and 3 mg, three times a day (total daily dose between 3 mg and 9 mg). However, some people may need to take more.

How to take it

You can take ROPIN with or without food. The tablets should be swallowed with water. Do not crush or chew the tablets.

ROPIN tablets can be broken in half if your doctor has prescribed half of a tablet.

When to take it

You need to take ROPIN three times a day. Do not take more than what your doctor has prescribed.

How long to take it

It may take a few weeks for your medicine to start to work. **Continue taking ROPIN for as long as your doctor recommends.**

Do not stop taking your medicine without consulting with your doctor first.

If you forget a dose

If a scheduled dose is missed, leave out that dose completely. Take your next dose at the normal time.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for advice.

While you are taking ROPIN

Things you must do

If you are about to be started on any new medicine, remind your doctor or pharmacist that you are taking ROPIN.

Tell all doctors, dentists and pharmacists who are treating you that you are taking ROPIN.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

Tell your doctor or pharmacist if you become pregnant while you are taking ROPIN.

Tell your doctor 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 ROPIN.

Your doctor may have to adjust or stop your dose.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not use ROPIN to treat any other complaints unless your doctor tells you to.

Do not give ROPIN to anyone else, even if his or her symptoms seem similar to yours.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Do not drive or operate machinery until you know how ROPIN affects you. Rarely, ROPIN can cause extreme sleepiness and sudden sleep onset episodes. If you start to suffer from extreme sleepiness or suddenly begin falling asleep without any apparent warning while taking ROPIN, do not drive or use machinery and avoid dangerous activities.

Things to be careful of

Be careful when drinking alcohol while you are taking ROPIN.

Combining alcohol with ROPIN can make you more sleepy, dizzy, or light-headed. Your doctor may suggest you avoid alcohol while taking this medicine.

Tell your doctor if you or your family notices that you are developing any unusual behaviour while you are taking ROPIN, such as an unusual urge to gamble or increased sexual urges and/or behaviours.

Your doctor may have to adjust or stop your dose.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well after taking ROPIN. All medicines can have some unwanted effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Feeling nauseous and vomiting
- Drowsiness
- Stomach ache or indigestion
- Feeling faint
- Nervousness
- Swelling of the legs.

The above list includes the more common side effects of your medicine.

Tell your doctor as soon as possible if you notice any of the following:

- Confusion or feeling, seeing or hearing things that are not there
- Extreme sleepiness and sudden sleep onset
- Uncontrollable twitching, jerking or writhing movements
- Feeling light-headed or dizzy, especially when getting up
- Developing any unusual behaviour, such as an unusual urge to gamble or increased sexual urges and/or behaviours.

The above list includes serious side effects. You may require urgent medical attention or hospitalisation.

Tell your doctor immediately if you notice any symptoms of an allergic reaction. Very rarely allergic reactions such as red, itchy swellings on the skin (hives), swelling of the

face, lips, mouth, tongue or throat may occur which may cause difficulty in swallowing or breathing, rash or intense itching.

This is not a complete list of all possible side effects. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Ask your doctor or pharmacist to answer any questions you may have.

In case of overdose

Immediately telephone your doctor or Poisons Information Centre (0800 POISON or 0800 764 766) for advice or go the Emergency department at your nearest hospital, if you think you may have taken too much or anyone else has taken any ROPIN by mistake, even if there are no signs of discomfort or poisoning. Urgent medical attention may be required. Take the pack of ROPIN with you if you can.

Keep telephone numbers for these places handy.

Storage conditions

Storage

Keep ROPIN where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep your tablets in the bottle until it is time to take them.

If you take the tablets out of the bottle they will not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store ROPIN or any other medicine in the bathroom or near a sink. Do not leave the tablets in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking ROPIN, or your medicine has passed its expiry date, ask your pharmacist what to do with any tablets that are left over.

Product Description

What ROPIN looks like

ROPIN tablets are available in five different strengths.

ROPIN 0.25 mg tablets are white to off white, capsule shaped, biconvex film-coated tablets, with a breakline on both sides.

ROPIN 0.5 mg tablets are yellow coloured, capsule shaped, biconvex film-coated tablets, with a breakline on both sides.

ROPIN 1 mg tablets are green coloured, capsule shaped, biconvex film-coated tablets, with a breakline on both sides.

ROPIN 2 mg tablets are pink coloured, capsule shaped, biconvex film-coated tablets, with a breakline on both sides.

ROPIN 5 mg tablets are blue coloured, capsule shaped, biconvex film-coated tablets, with a breakline on both sides.

The tablets are packed in bottles of 84 tablets.

Ingredients

Each ROPIN tablet contains the active ingredient ropinirole hydrochloride.

Each ROPIN film-coated tablet also contains the following inactive ingredients: lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, hypromellose, magnesium stearate and the contents of the film coat.

The film coat consists of hypromellose, macrogol 400, polysorbate and colouring agents titanium dioxide (0.25 mg, 0.5 mg, 2 mg, 5 mg), ferric oxide yellow (0.5 mg & 2 mg), spectracol green (1 mg), ferric oxide red (2 mg) and indigo carmine lake (5 mg).

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: (09) 579 2792

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2 February 2009
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