

ROPIN

Ropinirole hydrochloride 0.25, 1, 2 & 5 mg tablets

What is in this leaflet

Please read this leaflet carefully before you start taking ROPIN.

This leaflet answers some common questions about ROPIN.

It does not contain all the available information. It does not take the place of talking to 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 taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What ROPIN is used for

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 contains the active ingredient ropinirole hydrochloride. 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.

Your doctor may have prescribed this medicine for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

This medicine is available only with a doctor's prescription.

There is not enough information to recommend the use of this medicine for children under the age of 18 years.

Before you take ROPIN

When you must not take it

Do not take ROPIN if you have an allergy to:

- any medicine containing ropinirole hydrochloride
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take this medicine if you have liver problems.

Do not take this medicine if you have kidney problems that require you to have your blood purified regularly. Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

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

Before you start to take it

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

Patients with rare hereditary problems of galactose intolerance, total lactose deficiency or glucose-galactose malabsorption should not take this medicine

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

- heart problems
- kidney problems
- severe mental condition
- history of any unusual urges and/or behaviours (such as excessive gambling, excessive sexual behaviour, compulsive or binge eating or compulsive spending).

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

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. Your doctor can discuss with you the risks and benefits involved.

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 medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

You should also tell any health professional who is prescribing a new medication for you that you are taking ROPIN.

Some medicines may interfere with ROPIN. These include:

- neuroleptics and medicines used to treat mental conditions
- some antibiotics, such as ciprofloxacin and enoxacin
- fluvoxamine, a medicine usually taken for depression
- metoclopramide, a medicine usually taken for digestive disorders
- hormone replacement therapy

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 bottle, 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

Swallow the tablets with a full glass of 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

Take your medicine three times a day at about the same times each day.

Taking it at the same times each day will have the best effect. It will also help you to remember when to take them.

Take this medicine preferably with your meals to decrease the change of you getting unwanted side effects.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

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 to take it

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

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

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 some hints.

While you are taking ROPIN

Things you must do

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

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

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.

If you become pregnant while taking this medicine, tell your doctor immediately.

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

Your doctor may check your blood pressure or do some other tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

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

Do not give your medicine to anyone else, even if they have the same condition as you.

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

If you stop taking it suddenly, your condition may worsen or you may get unwanted side effects such as loss of motivation, anxiety, panic attacks, irritability, agitation, depression, fatigue, sweating, sleep disturbance or pain. If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

Things to be careful of

Be careful driving or operating machinery until you know how ROPIN affects you.

This medicine may cause dizziness, sleepiness, drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine.

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

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much ROPIN. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ROPIN.

This medicine helps most people with Parkinson's Disease, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

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

- nausea
- vomiting
- drowsiness
- stomach aches or indigestion
- heartburn
- feeling faint
- nervousness
- swelling of the legs, feet, ankles or hands

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
- feeling, seeing or hearing things that are not there
- aggression
- severe suspiciousness
- sleepiness and sudden sleep onset
- uncontrollable twitching, jerking or writhing movements
- feeling light-headed or dizzy, especially when getting up
- developing any unusual behaviour or thoughts, e.g. an unusual urge to gamble, increased sexual urges and/or behaviours, compulsive or binge eating or compulsive spending
- large swings in changes of mood, emotions or changes in energy level or activity level
- hallucinations

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- rash, lumps on the skin (hives) or intense itching
- swelling of the face, lips, mouth, tongue or throat
- difficulty in swallowing or breathing.

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

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. Tell your doctor if you notice any other effects.

Some side effects for example changes of your liver function can only be found when your doctor does tests from time to time to check your progress.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking ROPIN

Storage

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

If you take the tablets out of the bottle they may 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 it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it 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.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it 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 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.

Not all strengths may be marketed.

Date of Preparation

15 March 2022
(Based on datasheet dated 15
March 2022)

Ingredients

Active ingredient:

ROPIN contains 0.25 mg, 1 mg, 2 mg or 5 mg of ropinirole hydrochloride as the active ingredient.

Inactive ingredients:

ROPIN also contains:

- lactose monohydrate
- microcrystalline cellulose
- croscarmellose sodium
- hypromellose
- magnesium stearate.

- hypromellose
- macrogol 400
- titanium dioxide
- polysorbate (0.25 mg and 5 mg tablets)
- ferric oxide yellow (1 mg and 2 mg tablets),
- ferric oxide red (2 mg tablets)
- indigo carmine lake (1 mg and 5 mg tablets).

Contains sugars as lactose.

If you want to know more

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

Who supplies this medicine

ROPIN is supplied in New Zealand by:

Viatrix Ltd,
PO Box 11183,
Ellerslie,
Auckland
NEW ZEALAND
www.viatrix.co.nz
Telephone 0800 168 169