

Ropaccord Tablets 0.5 mg & 2 mg

Ropinirole (as Hydrochloride) Tablets

Consumer Medicine Information

What Is In This Leaflet

Please read this leaflet carefully before you use Ropaccord Tablets.

This leaflet answers some common questions about Ropaccord Tablets. It does not contain all of 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 expected benefits of you taking Ropaccord Tablets against the risks this medicine could 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 Ropaccord Tablets is used for?

The name of your medicine is Ropaccord Tablets; it is also known as ropinirole.

Ropaccord Tablets is used to treat restless legs syndrome.

Restless legs syndrome is a condition in which a sense of uneasiness, restlessness, and itching often accompanied by twitching and pain is felt in the legs and sometimes arms when sitting or lying down, especially in bed at night. The only relief is walking or moving the affected limbs, which often leads to problems sleeping at night time.

Restless legs syndrome is thought to be due to a deficiency in the body of a naturally occurring body chemical: dopamine.

Ropaccord Tablets belongs to a group of medicines called nonergoline, dopamine agonists.

Ropaccord Tablets works by having a similar effect on the body as dopamine, therefore it makes up for the dopamine shortage in restless legs syndrome. This in turn relieves the discomfort and reduces the involuntary limb movements that disrupt night time sleep.

Your doctor may have prescribed Ropaccord Tablets for another reason.

Ropaccord Tablets tablets are not addictive.

Before you take Ropaccord Tablets

Do not take if:

You must not take Ropaccord Tablets if:

- You have ever had an allergic reaction to ropinirole or any of the ingredients listed toward the end of this leaflet. (See "Ingredients")
- You are pregnant or intend to become pregnant
- You are breastfeeding or wish to breastfeed
- The expiry date (EXP) printed on the pack has passed.
- The packaging is torn or shows signs of tampering

Tell your doctor if:

You must tell your doctor if:

- You are allergic to foods, dyes, preservatives or any other medicines.

- You have any of these medical conditions:
 - Liver problems
 - Heart problems
 - Kidney problems
 - Blood pressure problems
 - A history of mental disorders
 - Neuroleptic-induced Akathisia (restlessness or difficulty keeping still, caused by medicines to treat mental disorders. This is a separate condition to restless legs syndrome)
- You are taking any other medicines, including medicines you buy without a prescription. Ropaccord Tablets may be affected by other medicines or vice versa.

These medicines include:

 - Theophylline (a medicine used to treat breathing difficulties)
 - Ciprofloxacin (an antibiotic)
 - Hormone replacement therapy (HRT)
 - Metoclopramide (a medicine to treat nausea and vomiting)
 - Fluvoxamine (a medicine that treats depression)
 - Neuroleptics (medicines to treat mental conditions)
- You start smoking or give up smoking while taking Ropaccord Tablets. Your doctor may need to adjust your dose.

If your symptoms get worse

In some people Ropaccord Tablets can make their symptoms of RLS get worse. See "If your symptoms get worse" under the section "While you are taking Ropaccord Tablets" and the information under "What are the Side Effects?".

Some medicines may affect the way other medicines work. Your doctor or pharmacist will be able to tell you which medicines are safe to take with Ropaccord Tablets.

How to I take Ropaccord Tablets?

Follow your doctor's instructions about how and when to take Ropaccord Tablets.

Read the direction label carefully. If you have any concerns about how to take Ropaccord Tablets, talk to your doctor or pharmacist.

How much to take

The starting dose is 0.25 mg once daily. After two days your doctor may increase your dose to 0.5 mg once daily for the remainder of your first week of treatment. After the first week, your doctor may continue to increase your dose gradually.

Your doctor may increase or decrease the amount that you are taking to give you the maximum benefit from the medicine. People generally experience benefit from taking 2 mg of Ropaccord Tablets a day.

However, some people need to take more or less than this amount.

How to take it

Take Ropaccord Tablets once a day.

Ropaccord Tablets is usually taken just before bedtime, but can be taken up to 3 hours before going to bed.

Swallow the Ropaccord Tablets tablet(s) whole with a glass of water. Do not chew the tablet(s). You can take Ropaccord Tablets with or without food. Taking Ropaccord Tablets with food may decrease the occurrence of nausea (feeling sick) which is a possible side effect of Ropaccord Tablets.

How long to take it for

Keep taking your Ropaccord Tablets for as long as your doctor tells you to. It may take a number of weeks for Ropaccord Tablets to work.

Do not stop taking Ropaccord Tablets even if you begin to feel better. For best effect Ropaccord Tablets must be taken regularly.

Do not stop taking Ropaccord Tablets, or change the dose without first checking with your doctor.

Use in children and elderly patients

Ropaccord Tablets is not recommended in children under the age of 18 years.

Elderly patients should follow the dosing instructions from your doctor or pharmacist.

If you forget to take it

Do not take an extra dose.

Wait until the next day and take your normal dose then.

Do not try to make up for the dose that you missed by taking more than one dose at a time.

If you have missed taking Ropaccord Tablets for more than a few days, consult your doctor for advice on restarting Ropaccord Tablets.

What do I do if I take too much? (Overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice if you think that you or anyone else may have taken too much Ropaccord Tablets. Do this even if there are no signs of discomfort or poisoning.

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

While you are taking Ropaccord Tablets

Things you must do

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.

Otherwise, your doctor may think that it was not working as it should and change your treatment unnecessarily.

Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use Ropaccord Tablets to treat any other complaints unless your doctor says so.

Things to be careful of

Driving/Operating Machinery:

Ropaccord Tablets may cause drowsiness in some people, especially at the start of treatment. If this occurs, you should not drive or operate machinery. In addition, some people may very rarely fall asleep suddenly without any apparent warning of sleepiness. If you feel excessive daytime sleepiness (somnia) or fall asleep suddenly without feeling sleepy, you must not drive or operate machinery until your doctor says you can. Make sure you know how Ropaccord Tablets affects you before you drive a car or operate machinery.

Use of Alcohol:

As with other drugs of this type, it is best to avoid alcohol while you are taking Ropaccord Tablets.

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 Ropaccord Tablets. Your doctor may have to adjust or stop your dose.

If your symptoms get worse

Some people taking Ropaccord Tablets 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.

What are the Side effects?

Check with your doctor as soon as possible if you think you are experiencing any side effects or allergic reactions due to taking Ropaccord Tablets, even if the problem is not listed below.

Like other medicines, Ropaccord Tablets can cause some side effects.

These are the more common side effects of Ropaccord Tablets and can occur at the start of therapy and/or on an increase of dose. They are generally mild and may become less after you have taken the medicine for a short time.

- Dizziness (or spinning sensation)
- Feeling drowsy/sleepy
- Nausea (feeling sick)
- Vomiting (being sick)
- Fatigue (mental or physical)
- Abdominal pain
- Fainting
- Nervousness
- 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).

Ropaccord Tablets can reduce blood pressure which may make you feel dizzy or faint especially when standing up from a sitting or lying position.

Very rarely Ropaccord Tablets can cause excessive daytime somnolence (drowsiness) and sudden sleep onset episodes where patients fall asleep suddenly without apparently feeling sleepy. If you feel extremely tired during the day or fall asleep suddenly without warning you should see your doctor as soon as possible.

Tell your doctor immediately if you notice any of the following:

- **Wheezing, swelling of the lips/mouth, difficulty in breathing, hay fever, lumpy rash (hives) or fainting. These could be a symptom of an allergic reaction.**

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

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

How do I store Ropaccord Tablets?

Storage

Keep this medicine where children cannot reach it, such as in a locked cupboard.

Keep Ropaccord Tablets tablets in a cool, dry place where it stays below 25°C.

Do not leave the tablets in a car, on a window sill or in the bathroom.

Keep Ropaccord Tablets in its blister/bottle pack until time to take them.

Return any unused or expired medicine to your pharmacist.

Product description

What it looks like

Ropaccord Tablets are available in the following strengths:

- **Ropaccord Tablets 0.5 mg**
Yellow, round, biconvex, film-coated tablets plain on both sides.
- **Ropaccord Tablets 2 mg**
Pink, round, biconvex, film-coated tablets plain on both sides.

Ropaccord Tablets 0.5 mg and 2 mg are available in aluminium blister packs containing 28 tablets and in HDPE bottles containing 84 tablets.

Ingredients

Ropaccord Tablets tablets contain the active ingredient Ropinirole (as Hydrochloride).

It also contains:

- Lactose
- Cellulose microcrystalline
- Croscarmellose sodium
- Magnesium stearate
- Hypromellose
- OPADRY complete film coating system 03B82930 YELLOW (0.5 mg) (ARTG 12851)
- OPADRY complete film coating system 03B54094 PINK (2 mg) (ARTG 12850).

Name and Address of the Sponsor

Accord Healthcare Pty Ltd.

Unit 702/23
Queens Road
Melbourne, Victoria, 3004
Australia

Name and Address of the Distributor

Ranbaxy Australia Pty Ltd

Suite 4.02, Building D, Level 4
12-24 Talavera Road
North Ryde, NSW 2113
Australia

Ropaccord Tablets 0.5 mg:

AUST R 157772 (Blister)
AUST R 157770 (Bottle)

Ropaccord Tablets 2 mg:

AUST R 157767 (Blister)
AUST R 157765 (Bottle)

Date of Approval

TGA approval: 23rd July 2010

This leaflet was prepared in April 2011.