

## ROPINIROLE-GA

*Ropinirole (as hydrochloride)*

### Consumer Medicine Information

#### What is in this leaflet?

Please read this leaflet carefully before you use Ropinirole-GA tablets.

This leaflet answers some common questions about Ropinirole-GA 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 Ropinirole-GA 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 is Ropinirole-GA used for?

The name of your medicine is Ropinirole-GA; it is also known as ropinirole.

Ropinirole-GA 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.

Ropinirole-GA belongs to a group of medicines called non-ergoline, dopamine agonists. Ropinirole-GA 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 Ropinirole-GA for another reason.

Ropinirole-GA tablets are not addictive.

#### Before you take Ropinirole-GA

##### *Do not take if:*

You must not take Ropinirole-GA 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. Ropinirole-GA 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 Ropinirole-GA. Your doctor may need to adjust your dose.

##### *If your symptoms get worse*

In some people Ropinirole-GA can make their symptoms of RLS get worse. See "If your symptoms get worse" under the section "While you are taking Ropinirole-GA" 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 Ropinirole-GA.

#### How do I take Ropinirole-GA?

Follow your doctors' instructions about how and when to take Ropinirole-GA.

Read the direction label carefully. If you have any concerns about how to take Ropinirole-GA, 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 2mg of Ropinirole-GA a day.

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

##### *How to take it*

Take Ropinirole-GA once a day. Ropinirole-GA is usually taken just before bedtime, but can be taken up to 3 hours before going to bed.

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

##### *How long to take it for*

Keep taking your Ropinirole-GA for as long as your doctor tells you to. It may take a number of weeks for Ropinirole-GA to work.

Do not stop taking Ropinirole-GA even if you begin to feel better. For best effect Ropinirole-GA must be taken regularly.

Do not stop taking Ropinirole-GA, or change the dose without first checking with your doctor.

##### *Use in children and elderly patients*

Ropinirole-GA 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 Ropinirole-GA for more than a few days, consult your doctor for advice on restarting Ropinirole-GA.

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

**Immediately telephone your doctor or Poisons Information Centre (telephone 131126) for advice, if you think you or anyone else may have taken too much Ropinirole-GA, 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 Ropinirole-GA

##### *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 Ropinirole-GA to treat any other complaints unless your doctor says to.**

##### *Things to be careful of*

###### **Driving/Operating Machinery:**

Ropinirole-GA 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 Ropinirole-GA 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 Ropinirole-GA.

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, compulsive shopping and binge eating) while you are taking Ropinirole-GA. Your doctor may have to adjust or stop your dose.

#### **If your symptoms get worse**

Some people taking Ropinirole-GA 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.

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#### **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 Ropinirole-GA, even if the problem is not listed below.**

Like other medicines, Ropinirole-GA can cause some side effects.

These are the more common side effects of Ropinirole-GA 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).

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

Very rarely Ropinirole-GA 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.

The following rare mental side effects have been reported in patients:

- Compulsive behaviour such as gambling, increase sex drive, shopping eating.
- hallucinations, delusions, paranoia, delirium, impulse control symptoms and aggression.

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

- **Wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, 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.**

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#### **How do I store Ropinirole-GA?**

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

**Keep Ropinirole-GA 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 Ropinirole-GA tablets in its blister pack until time to take them.**

**Return any unused or expired medicine to your pharmacist.**

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#### **Product description**

##### *What it looks like*

Ropinirole-GA comes as a pentagonal shaped "Tiltab" tablet, containing ropinirole. The tablets are available in the following strengths:

- pale yellow tablets containing 0.5 mg ropinirole, marked "SB" on one side and "4891" on the other.
- pale yellowish pink tablets containing 2 mg ropinirole, marked "SB" on one side and "4893" on the other.

The 0.5 mg and 2 mg strengths are available in packs of 28 tablets.

##### *Ingredients*

Ropinirole-GA tablets contain the active ingredient ropinirole (as hydrochloride).

Ropinirole-GA tablets also contain lactose, cellulose micro-crystalline, croscarmellose sodium, magnesium stearate, hypromellose, macrogol 400 and titanium dioxide as excipients. Colouring agents are also contained in the film coating as follows:

- 0.5mg tablets (pale yellow) contain iron oxide yellow CI77492, iron oxide red CI77491, indigo carmine CI73015 and aluminium.
- 2.0mg tablets (pale yellowish pink) contain iron oxide yellow CI77492 and iron oxide red CI77491.

##### *Supplier*

Your Ropinirole-GA tablets are supplied by:

**Actavis Pty Ltd**  
Level 5, 117 Harrington St  
The Rocks, NSW 2000

For further information call 1800 554 414.

This leaflet was updated in May 2014.

The information provided applies only to Ropinirole-GA tablets.

**Ropinirole-GA tablets 0.5 mg:**

AUST R 189856

**Ropinirole-GA tablets 2 mg:**

AUST R 190143

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