

REPREVE®

Ropinirole (as hydrochloride)

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you use REPREVE tablets.

This leaflet answers some common questions about REPREVE 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 REPREVE 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 REPREVE used for?

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

REPREVE 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.

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

REPREVE tablets are not addictive.

Before you take REPREVE

Do not take if:

You must not take REPREVE 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. REPREVE 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 REPREVE. Your doctor may need to adjust your dose.

If your symptoms get worse

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

How do I take REPREVE?

Follow your doctors' instructions about how and when to take REPREVE.

Read the direction label carefully. If you have any concerns about how to take REPREVE, 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 REPREVE a day.

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

How to take it

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

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

How long to take it for

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

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

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

Use in children and elderly patients

REPREVE 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 REPREVE for more than a few days, consult your doctor for advice on restarting REPREVE

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 you or anyone else may have taken too much REPREVE, 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 REPREVE

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 REPREVE to treat any other complaints unless your doctor says to.

Things to be careful of

Driving/ Operating Machinery:

REPREVE 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 (somnolence) 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 REPREVE 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 REPREVE.

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 REPREVE. Your doctor may have to adjust or stop your dose.

If your symptoms get worse

Some people taking REPREVE find

that their RLS symptoms get worse, for example the 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 REPREVE, even if the problem is not listed below.

Like other medicines, REPREVE can cause some side effects.

These are the more common side effects of REPREVE 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).

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

Very rarely REPREVE 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 in 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.

How do I store REPREVE?

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

Keep REPREVE tablets in a cool, dry place where it stays below 25 degrees C.

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

Keep REPREVE tablets in its blister pack until time to take them.

Return any unused or expired medicine to your pharmacist.

Product description

What it looks like

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

- white tablets containing 0.25 mg ropinirole, marked "SB" on one side and "4890" on the other.
- 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 0.25 mg strength is available in packs of 12 tablets. The 0.5 mg and 2 mg strengths are available in packs of 28 tablets.

Ingredients

REPREVE tablets contain the active ingredient ropinirole (as hydrochloride).

REPREVE tablets also contain lactose monohydrate, cellulose micro-crystalline, croscarmellose sodium, magnesium stearate, hypromellose, macrogol 400 and titanium dioxide as excipients. The 0.25mg tablets also contain polysorbate 80 as an excipient.

Colouring agents are also contained in the film coating as follows:

- 0.25mg tablets (white) contain titanium dioxide CI77891.
- 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 REPREVE tablets are supplied by:

Arrow Pharma Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121
Australia.

*Where to go for further
information*

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition. You may also be able to find general information about your disease and its treatment from patient information groups eg. Sleep Disorder Australia

This leaflet was updated in:
May 2016

The information provided applies only to REPREVE® tablets.

REPREVE tablets 0.25 mg:
AUST R 96866

REPREVE tablets 0.5 mg:
AUST R 96868

REPREVE tablets 2 mg:
AUST R 96870

Version 5.0