

REPREVE

ropinirole (as hydrochloride)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about REPREVE.

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 benefits and risks. Your doctor has weighed the risks of you taking REPREVE against the benefits they expect it will have for you.

Talk to your doctor or pharmacist if you have any concerns about taking this medicine.

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

What REPREVE is used for

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 dopamine, a naturally occurring body chemical.

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.

REPREVE is not recommended for use in children or adolescents (under the age of 18), as there have been no studies of its effects in this age group).

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

There is no evidence that it is addictive.

Before you take it

When you must not take it

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

Do not take it if you are pregnant or intend to become pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not take it if you are breastfeeding.

REPREVE passes into breast milk and may affect your baby.

Do not take it if the expiry date (Exp.) printed on the pack has passed.

Do not take it if the packaging is torn or shows signs of tampering.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

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

- liver problems
- kidney problems
- heart 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).

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

Taking other medicines

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

Some medicines may be affected by REPREVE, or may affect how well it works. These include:

- Central Nervous System depressants, e.g. Benzodiazepines, antipsychotics, or antidepressants
- fluvoxamine, a medicine to treat depression.
- neuroleptics, medicines to treat mental disorders, for example sulpiride.

- metoclopramide, a medicine used to treat nausea or vomiting.
- theophylline, a medicine used to treat breathing difficulties.
- ciprofloxacin, an antibiotic
- hormone replacement therapy (HRT).

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

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

If you start smoking or give up smoking while taking REPREVE, your doctor may also need to adjust your dosage.

If your symptoms get worse

In some people REPREVE can make their symptoms of restless legs syndrome get worse. See “If your symptoms get worse” under “While you are taking it” and the information under “Side effects”.

How to take it

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.

Follow all directions given to you by your doctor and pharmacist carefully.

How to take it

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

Swallow tablet(s) whole with a glass of water. You can take this medicine with or without food.

Taking it with food may decrease the occurrence of nausea (feeling sick) which is a possible side effects.

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

How long to take it for

Keep taking your medicine for as long as your doctor tells you to.

It may take a number of weeks for it to work.

Do not stop taking it even if you begin to feel better.

For best effect it must be taken regularly.

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

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or

anyone else may have taken too much REPREVE. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking it

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking REPREVE.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking this medicine.

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.

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

Things you must not do

Do not use it to treat any other conditions unless your doctor tells you to.

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

Things to be careful of

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

It may cause drowsiness in some people, especially at the start of treatment. If this occurs, do not drive, operate machinery or do anything else that could be dangerous.

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 this medicine affects you before you drive a car or operate machinery.

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

Tell your doctor if you experience symptoms such as depression, apathy, anxiety, fatigue, sweating or pain after stopping or reducing your REPREVE treatment (called dopamine agonist withdrawal syndrome or DAWS).

If the problems persist more than a few weeks, your doctor may need to adjust your dose.

Tell your doctor if you or your family/carer notices that you are developing urges or cravings to behave in ways that are unusual for you, and you cannot resist the impulse, drive or temptation to carry out certain activities that could harm yourself or others. These are called impulse control disorders and can include behaviours such as addictive gambling, excessive eating or spending, an abnormally high sex drive or an increase in sexual thoughts or feelings.

Your doctor may need to adjust or stop your dose.

Tell your doctor if you or your family/carer notices that you are developing episodes of overactivity, elation or irritability (symptoms of mania). These may occur with or without the symptoms of impulse control disorders (see above).

Your doctor may need to adjust or stop your dose.

If your symptoms get worse

Some people taking REPREVE find that their restless legs syndrome 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.

Side effects

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

Like all other medicines, it may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

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

- dizziness
 - feeling drowsy
 - nausea
 - vomiting
 - fatigue, either mental or physical
 - abdominal pain
 - fainting
 - nervousness
 - apathy
 - anxiety
 - depression
 - sweating
 - heartburn
 - worsening of restless legs syndrome (symptoms may: start earlier than usual, be more intense, affect other parts of the body - such as the arms, or return in the early morning).
 - Hiccups
 - Spontaneous penile erection
- REPREVE can reduce blood pressure which may make you feel dizzy or faint especially when

standing up from a sitting or lying position.

This medicine can very rarely 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:

- swelling of your lower legs or hands
- wheezing, swelling of the lips/mouth, difficulty breathing, hayfever, lumpy rash (hives) or fainting. These could be symptoms of an allergic reaction.

Tell your doctor if you notice anything that is making you feel unwell. Other side effects not listed above may also occur in some patients.

After using it

Storage

Keep your medicine 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 pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

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

Do not store REPREVE or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking REPREVE, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

REPREVE comes in 2 strengths of tablets:

- REPREVE 0.25- White to off-white, pentagon shaped tablet with 'RI' over '25' on one side and plain on the other side.
- REPREVE 0.5 - Yellow, pentagon shaped tablet with 'RI' over '50' on one side and plain on the other side
- REPREVE 2 - Pink, pentagon shaped tablet with 'RI' over '2' on one side and plain on the other side

Each pack contains 28 tablets.

Ingredients

The active ingredient in REPREVE is ropinirole (as ropinirole hydrochloride).

- Each REPREVE 0.25 tablet contains 0.25 mg ropinirole
- each REPREVE 0.5 tablet contains 0.5 mg of ropinirole
- each REPREVE 2 tablet contains 2 mg of ropinirole.

The tablets also contain:

- lactose monohydrate
- microcrystalline cellulose
- croscarmellose sodium

- magnesium stearate
- Opadry II 85F18378 White (0.25 mg only)
- Opadry II 85F62505 Yellow (0.5 mg)
- Opadry II 85F64712 Pink (2 mg only).

The tablets do not contain gluten, sucrose, tartrazine or any other azo dyes.

Contains sugars as lactose (0.25 mg and 0.5 mg).

Supplier

Arrotex Pharmaceuticals Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121
Australia

Australian registration numbers:

REPREVE 0.25 mg AUST R
295481

REPREVE 0.5 mg - AUST R
295482

REPREVE 2 mg - AUST R 295484

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