

REPREVE

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using REPREVE ?

REPREVE contains the active ingredient ropinirole hydrochloride. REPREVE is used to treat restless legs syndrome.

For more information, see Section [1. Why am I using REPREVE ?](#) in the full CMI.

2. What should I know before I use REPREVE ?

Do not use if you have ever had an allergic reaction to Repreve or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use REPREVE ?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with REPREVE and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use REPREVE ?

- The doctor will tell you how much REPREVE to take to provide maximum benefit

More instructions can be found in Section [4. How do I use REPREVE ?](#) in the full CMI.

5. What should I know while using REPREVE ?

| | |
|------------------------------------|---|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using REPREVE• Tell your doctor immediately if you become pregnant while using REPREVE |
| Things you should not do | <ul style="list-style-type: none">• Do not use it to treat any other conditions• Do not give to anyone else even if they have the same condition as you |
| Driving or using machines | Be careful until you know how REPREVE affects you. It may cause drowsiness in some people, especially at the start of treatment |
| Drinking alcohol | <ul style="list-style-type: none">• Advise avoiding drinking alcohol while taking REPREVE |
| Looking after your medicine | <ul style="list-style-type: none">• Store in a cool dry place below 25°C |

For more information, see Section [5. What should I know while using REPREVE?](#) in the full CMI.

6. Are there any side effects?

Some of the Less serious side effects; dizziness, feeling drowsy, nausea, vomiting. Serious side effects: swelling of lower legs, hand lips/mouths, wheezing, hay fever, lumpy rash (hives) or fainting

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

REPREVE

Active ingredient(s): *Ropinirole hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using REPREVE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using REPREVE.**

Where to find information in this leaflet:

- [1. Why am I using REPREVE ?](#)
- [2. What should I know before I use REPREVE ?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use REPREVE ?](#)
- [5. What should I know while using REPREVE ?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using REPREVE ?

REPREVE contains the active ingredient **ropinirole hydrochloride**. REPREVE belongs to a group of medicines called **non-ergoline, dopamine agonist**. It 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 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.

2. What should I know before I use REPREVE ?

Warnings

Do not use REPREVE if:

- you are allergic to ropinirole, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other 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).

- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

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.

Other warnings

- 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.
- 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".

3. What if I am taking other medicines?

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

Some medicines may interfere with REPREVE and affect how it works.

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect REPREVE.

4. How do I use REPREVE ?

How much to take / use

- 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 the instructions provided and use REPREVE until your doctor tells you to stop.

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

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

When to take / use REPREVE

REPREVE should be taken 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.

If you forget to use REPREVE

REPREVE should be used regularly at the same time each day.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

If you have missed a dose for more than a few days, consult your doctor for advice on restarting REPREVE

If you use too much REPREVE

If you think that you have used too much REPREVE, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or

- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using REPREVE ?

Things you should do

Call your doctor straight away if you:

- 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.
- become pregnant while taking it, tell your doctor immediately.
- **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.

Remind any doctor, dentist or pharmacist you visit that you are using REPREVE.

Things you should 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 you should be careful of

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.
- 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.
- 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how REPREVE affects you.

REPREVE may cause dizziness 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

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

Looking after your medicine

- Store below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

| Less serious side effects | What to do |
|--|--|
| <ul style="list-style-type: none"> • dizziness (blood pressure may decrease, which may make you feel dizzy or faint especially when standing up from a sitting or lying position) | <p>Speak to your doctor if you have any of these less</p> |

| | |
|---|--|
| <ul style="list-style-type: none"> • feeling drowsy or sudden sleep onset • 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 <p>Mental/psychiatric</p> <p>rare mental side effects have been reported in patients:</p> <ul style="list-style-type: none"> • compulsive behaviour such as gambling, increase in sex drive, shopping, binge and compulsive eating. • hallucinations, delusions, paranoia, delirium, impulse control symptoms and aggression. | <p>serious side effects and they worry you.</p> |
|---|--|

Serious side effects

| Serious side effects | What to do |
|---|--|
| <ul style="list-style-type: none"> • swelling of your lower legs or hands • wheezing, swelling of the lips/mouth, difficulty breathing, hay fever, lumpy rash (hives) or fainting. These could be symptoms of an allergic reaction. | <p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> |

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the

Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What REPREVE contains

| | |
|---|---|
| Active ingredient (main ingredient) | Each Repreve tablet contains either- <ul style="list-style-type: none">- Ropinirole (as hydrochloride) 0.25 mg- Ropinirole (as hydrochloride) 0.5 mg- Ropinirole (as hydrochloride) 2 mg |
| Other ingredients (inactive ingredients) | <ul style="list-style-type: none">• 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). |
| Potential allergens | Contains sugars as lactose (0.25 mg and 0.5 mg) |

Do not take this medicine if you are allergic to any of these ingredients.

What REPREVE looks like

REPREVE 0.25 is a White to off-white, pentagon shaped tablet with 'RI' over '25' on one side and plain on the other side. (Aust R 295481).

REPREVE 0.5 is a Yellow, pentagon shaped tablet with 'RI' over '50' on one side and plain on the other side. (Aust R 295482).

REPREVE 2 is a Pink, pentagon shaped tablet with 'RI' over '2' on one side and plain on the other side (Aust R 295484).

Each pack contains 28 tablets.

Who distributes REPREVE

Arrotex Pharmaceuticals Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121
Australia
www.arrotex.com.au

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