

RAMIPEX 0.25 mg & 1 mg Tablets
Pramipexole hydrochloride

DEVATIS

Consumer Medicine Information (CMI)

What is in this leaflet

Please read this leaflet carefully before you start using RAMIPEX Tablets.

This leaflet answers some common questions about RAMIPEX Tablets. It does not contain all 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 risks of you being given RAMIPEX Tablets against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, talk to your doctor or pharmacist.

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

What RAMIPEX Tablets is used for

Each RAMIPEX tablet contains the active ingredient pramipexole dihydrochloride. Pramipexole dihydrochloride belongs to a group of medicines known as "dopamine agonists".

RAMIPEX is used to treat the symptoms of Parkinson's disease and Restless Legs Syndrome (RLS).

Parkinson's Disease

Parkinson's disease is a disease of the brain that affects body movement.

The symptoms of Parkinson's disease are caused by a lack of dopamine, a naturally occurring chemical produced by certain brain cells. Dopamine relays messages in the part of the brain that controls movement. When too little dopamine is produced, this results in Parkinson's disease. RAMIPEX Tablets works by having a similar effect as dopamine in the brain.

Restless Legs Syndrome (RLS)

RLS is a neurological disorder in which there is an overwhelming urge to move the legs to stop unpleasant sensations.

The sensations vary from person to person and range from uncomfortable to irritating to painful. The symptoms usually occur when sitting or lying down – which often leads to problems falling or staying asleep. Sometimes the arms and body may be affected. Current evidence suggests that RLS may be due to faulty dopamine signals in certain areas of the brain.

Your doctor may have prescribed RAMIPEX Tablets for another reason.

Ask your doctor if you have any questions about why RAMIPEX Tablets has been prescribed for you.

This medicine is available only with a doctor's prescription.
There is no evidence that it is addictive.

Before you take RAMIPEX Tablets

When you must not take it

Do not take RAMIPEX if you are allergic to pramipexole or any of the other ingredients listed at the end of this leaflet.

If you are not sure if you have these allergies, you should raise those concerns with your doctor.

Signs of an allergic reaction may include itching of skin, shortness of breath and swelling of the tongue or face.

You should not use RAMIPEX after the EXPIRY DATE on the carton or blister strips, or if the packaging is torn or damaged.

If you are not sure whether you should be given RAMIPEX Tablets, talk to your doctor.

Before you start to use it

It is essential that your doctor knows your medical history before prescribing RAMIPEX.

Before taking this medicine, you must tell your doctor if you have, or have had, any of the following conditions:

- kidney problems
- mental illnesses
- low blood pressure
- trouble controlling your muscles (dyskinesia)

If you are not sure if you have, or have had, any of these conditions, you should raise those concerns with your doctor.

If you have not told your doctor about any of the above, tell them before you start being given RAMIPEX Tablets.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking RAMIPEX Tablets.

In particular, you should tell your doctor if you are taking:

- levodopa, levodopa/carbidopa combination, or other medicines used to treat Parkinson's disease (e.g. amantadine)
- medicines used in the treatment of high blood pressure or heart problems (e.g. digoxin, diltiazem, procainamide, quinidine, triamterene, verapamil, hydrochlorothiazide)
- medicines used in the treatment of mental illness/psychosis
- metoclopramide - commonly used to help control nausea and vomiting
- cimetidine or ranitidine - used to treat stomach or duodenal ulcer
- quinine - used to prevent malaria
- some antibiotics (e.g. trimethoprim, cephalosporins, penicillins)
- indomethacin, a medicine used to treat arthritis
- chlorpropamide, a medicine used to treat diabetes
- other medicines that can cause drowsiness or sleepiness (e.g. antihistamine or some cough and cold preparations)

These medicines may be affected by RAMIPEX Tablets or may affect how well it works. You may need different amounts of the medicine, or you may need to take different medicines. Your doctor or pharmacist

will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking RAMIPEX Tablets.

Ask for your doctor's advice if you are pregnant, or likely to become pregnant during your course of medication.

Your doctor can discuss with you the benefits and risks of taking RAMIPEX Tablets.

Ask for your doctor's advice if you are breastfeeding, or likely to breastfeed during your course of medication.

RAMIPEX is not recommended during breastfeeding, as it may pass into breast milk.

Use in Children

The use of RAMIPEX is not recommended in children below 18 years of age.

How to take RAMIPEX Tablets

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

They may differ from the information contained in this leaflet.

RAMIPEX is available in a number of tablet strengths. Your doctor or pharmacist will tell you which strength of RAMIPEX tablet and how many tablets you will need to take each day. This depends on your condition and whether or not you are taking any other medicines.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How much to take

The dose varies from patient to patient. Your doctor may first start you on a low dose of RAMIPEX tablet and slowly increase the amount of RAMIPEX tablet until the right dose is reached to control your condition.

Parkinson's Disease

The usual starting dose is one 0.125 mg tablet three times a day.

Depending on how you respond to the treatment, your doctor may increase your daily dose gradually in steps of 0.75 mg at weekly intervals until the right dose for your needs is reached. The maximum dose is 4.5 mg of RAMIPEX per day.

Restless Legs Syndrome

The usual starting dose is one 0.125 mg tablet once a day, usually 2 to 3 hours before you go to bed.

Depending on how you respond to the treatment, your doctor may increase your dose gradually every 4 to 7 days until the right dose for your needs is reached. The maximum dose is 0.75 mg of RAMIPEX per day.

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

How to take it

Swallow the tablets with a full glass of water.

RAMIPEX can be taken with or without food.

When to take it

Take RAMIPEX at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it

Continue taking RAMIPEX for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

Parkinson's Disease

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

Otherwise, take it as soon as you remember, then go back to taking it as you would normally.

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

This may increase the chance of you getting an unwanted side effect.

Restless Legs Syndrome

If you forget to take pramipexole tablet before you go to bed and you wake up late in the night or early morning, do not take any pramipexole tablet as you may have trouble waking in the morning.

Skip the dose you missed and take the next dose when you are meant to.

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

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

While you are taking RAMIPEX Tablets

Things you must do

Tell all doctors and pharmacists who are treating you that you are taking RAMIPEX Tablets.

Tell your doctor or pharmacist if you feel that RAMIPEX Tablets are not helping your condition.

Tell your doctor if, for any reason, you have not used RAMIPEX Tablets exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor as soon as possible if there is any worsening of your condition.

If you or your family notices an increase in compulsive behaviour, seek immediate medical advice.

Things you must not do

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

Do not stop taking RAMIPEX Tablets or change the dose without checking with your doctor.

It is important not to suddenly stop taking your RAMIPEX Tablets, unless advised to do so by your doctor. If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects.

If you are using RAMIPEX Tablets for your Parkinson's Disease and your doctor asks you to stop taking RAMIPEX Tablets, the dose will normally be reduced gradually over several days.

Things to be careful of

Do not drive a car, operate machinery, or do anything else that could be dangerous (after taking RAMIPEX Tablets) until you know how the medicine affects you.

It may cause drowsiness, hallucinations and episodes of sudden onset of sleep, in some people.

Make sure you know how you react to it before you engage in any activities where impaired alertness may put yourself or others at risk of serious injury.

If you experience excessive drowsiness or an episode of sudden onset of sleep (while performing daily activities), do not drive or perform any potentially dangerous activities, and contact your doctor.

Be careful when drinking alcohol while taking RAMIPEX Tablets. Combining it and alcohol can make you more drowsy or sleepy.

Be careful getting up from a sitting or lying position.

You may feel dizzy or lightheaded while taking RAMIPEX Tablets, especially during the first few weeks of treatment. If you wish to stand up, you should do so slowly.

Patients with Parkinson's Disease may have an increased risk of developing melanoma.

You should monitor your skin and see your doctor in case of any concerns.

In case of overdose

If you take too much RAMIPEX (overdose)

Immediately telephone your doctor, pharmacist or New Zealand National Poisons Centre (telephone 0800 764-766) for advice, or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much RAMIPEX Tablets. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Signs of overdose may include nausea, vomiting, abnormal uncontrolled movements, hallucinations, agitation and dizziness or light-headedness.

Side effects

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

RAMIPEX Tablets helps most people with Parkinson's disease or RLS, but it may have unwanted side effects in a few people. All medicines can have side effects. 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 these lists 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:

- feeling sick (nausea)
- vomiting
- constipation
- diarrhoea
- dry mouth
- drowsiness
- tiredness
- confusion or hallucinations (seeing, feeling or hearing things that are not there)
- restlessness

- dizziness
- headache
- light-headedness on standing up, especially when getting up from a sitting or lying position (hypotension)
- blurred vision
- swelling of hands, ankles or feet (peripheral oedema)
- uncontrollable twitching, jerking or writhing movements (dyskinesia)
- difficulty sleeping or unusual dreams
- weight gain or loss
- loss or gain of sexual drive

Some of these side effects are more common at the start of treatment and lessen or disappear with time.

Tell your doctor immediately if you or your family notice any of the following side effects:

- loss of memory (amnesia)
- fainting
- signs of allergy such as rash or hives on the skin; swelling of the face, lips, tongue or other parts of the body; wheezing or difficulty breathing
- excessive sleepiness or sudden onset of sleep during normal daily activities
- compulsive behaviour such as gambling, hypersexuality, shopping, eating, medication use and repetitive purposeless activities
- mental illness causing severe suspiciousness (paranoia)
- shortness of breath or tightness in the chest (dyspnoea)
- shortness of breath, swelling of the feet or legs due to fluid build-up (heart failure)

Tell your doctor if you notice anything else that is making you feel unwell, even if you think the problems are not connected with this medicine and are not referred to in this leaflet.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

After using RAMIPEX Tablets

Storage

Keep RAMIPEX in the pack until it is time to take it.

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

Do not store your RAMIPEX in direct sunlight or heat.

For example, do not leave your RAMIPEX in the car on hot days.

Keep the medicine where children cannot reach it.

Disposal

Do not use RAMIPEX Tablets after the expiry date, which is stated on the packaging.

If your doctor advises you to stop taking RAMIPEX Tablets or the medicine has passed its expiry date, ask your pharmacist how to throw away medicines you no longer use. Do not throw away any medicines via wastewater. These measures will help protect the environment.

Product description

What it looks like

RAMIPEX 0.25 mg Tablets are white, oblong tablets with break line in one side and the other side plain and are available in blister packs of 30 and 100 tablets.

RAMIPEX 1 mg Tablets are white, round tablets with break line in one side and the other side plain and are available in blister packs of 30 and 100 tablets.

All tablets can be divided into equal halves.

Ingredients

Active ingredient(s):

Each 0.25 mg RAMIPEX tablet contains pramipexole dihydrochloride monohydrate 0.25 mg.

Each 1 mg RAMIPEX tablet contains pramipexole dihydrochloride monohydrate 1 mg.

Inactive ingredients:

Maize starch

Mannitol

Povidone

Colloidal anhydrous silica

Magnesium stearate

Sponsor

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