

APO-PRAMIPEXOLE ER

Modified release tablets

Pramipexole dihydrochloride monohydrate

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about pramipexole. 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 using this medicine against the benefits they expect it will 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 want to read it again.

What this medicine is used for

Pramipexole is used to treat symptoms of Parkinson's disease.

It belongs to a group of medicines known as dopamine agonists.

How it works

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 binds to dopamine receptors and relays messages in the part of the brain that controls movement. When too little dopamine is produced, this results in Parkinson's disease. Pramipexole works by having a similar effect as dopamine in the brain.

Pramipexole ER contains the active ingredient pramipexole dihydrochloride monohydrate. It belongs to a group of medicines known as dopamine agonists, which bind to dopamine receptors.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed this medicine for another reason.

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

This medicine is not addictive.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- any medicine containing pramipexole dihydrochloride monohydrate (the active ingredient) or
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin.

Do not give this medicine to a child or adolescent under the age of 18 years.

Safety and effectiveness in children younger than 18 years have not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

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

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

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Your doctor can discuss with you the benefits and risks involved. This medicine is not recommended during breastfeeding as it may pass into breast milk and there is a possibility that your baby may be affected

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

Taking other medicines

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

Some medicines and pramipexole may interfere with each other. These include:

- levodopa, levodopa/carbidopa combination, or other medicines used to treat Parkinson's disease (e.g. amantadine)
- medicines used to treat high blood pressure or heart problems (e.g. digoxin, diltiazem, procainamide, quinidine, triamterene, verapamil, hydrochlorothiazide)
- medicines used to treat mental illness/psychoses (such as antipsychotics or neuroleptics)
- metoclopramide, a medicine used to treat nausea and vomiting
- cimetidine and ranitidine, medicines used to treat stomach or duodenal ulcers
- quinine, a medicine used to prevent malaria
- some antibiotics such as trimethoprim, cephalosporins, penicillins
- indometacin, a medicine used to treat arthritis
- chlorpropamide, a medicine used to treat diabetes
- medicines that can cause drowsiness (e.g. sleeping tablets, pain killers, antihistamines or some cough and cold preparations).

These medicines may be affected by this medicine or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

Other medicines not listed above may also interact with pramipexole.

How to take this medicine

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

They may differ from the information contained in this leaflet.

Pramipexole ER is available in a number of tablet strengths. Your doctor or pharmacist will tell you 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 box, ask your doctor or pharmacist for help.

How much to take

The usual dose for an adult is one tablet a day.

Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.

If you are switching from the pramipexole immediate-release (IR) tablets:

Your doctor will base your dose of pramipexole ER tablets on your current dose of pramipexole IR tablets.

Take your pramipexole IR tablets as normal the day before you switch. Take your pramipexole ER tablets the next morning and do not take any more pramipexole IR tablets.

How to take it

Swallow the tablets whole with a full glass of water.

Do not chew, divide or crush pramipexole ER tablets.

It does not matter if you take this medicine with or without food

When to take it

Take your medicine 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 for

Continue taking your medicine 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.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

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

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

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

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

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.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) 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 of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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

While you are taking this medicine

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

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

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

Keep all of your doctor's appointments so that your progress can be checked.

Tell your doctor if, for any reason, you have not used Pramipexole ER 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.

Tell your doctor if you notice parts of pramipexole ER tablets in your stool (faeces). This may look like whole tablets. Your doctor may need to assess your response to therapy.

Tell your doctor if you experience symptoms such as depression, apathy, anxiety, fatigue, sweating or pain after stopping or reducing your pramipexole treatment.

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

Tell your doctor if you develop an inability to keep your body and neck straight and upright. This may include abnormal posture such as forward bending of the head and neck, forward bending of the lower back or sideways bending of the back.

Things you must not do

Do not take this medicine to treat any other complaints unless your doctor tells you to.

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

Do not stop taking your medicine or lower the dosage without checking with your doctor.

It is important not to suddenly stop taking your pramipexole ER tablets, unless advised to do so by your doctor, since your condition may worsen. If your doctor asks you to stop taking pramipexole ER tablets, the dose will normally need to be reduced gradually over several days.

Things to be careful of

Be careful driving or operating machinery until you know how this medicine affects you. This medicine may cause drowsiness, hallucinations and episodes of sudden onset of sleep in some people.

Make sure you know how you react to Pramipexole ER 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. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while taking pramipexole.

Combining pramipexole 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 pramipexole, especially during the first few weeks of treatment. If you wish to stand up, you should do so slowly.

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

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

Side effects

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

Pramipexole helps most people with Parkinson's disease, 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 attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

Tell your doctor or pharmacist 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
- headache
- dizziness, 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
- forward bending of the head and neck

The above list includes the more common side effects of your medicine. Some of these side effects are more common at the start of treatment and lessen or disappear with time.

- Tell your doctor as soon as possible if you notice any of the following 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)

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some patients.

After taking this medicine

Storage

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

Do not store your medicine or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it 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.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What APO-Pramipexole ER looks like

Pramipexole dihydrochloride monohydrate 0.375 mg modified-release tablets:

White or nearly white, cylindrical, plans and bevel tablets marked with 026 on one side. AUST R 225622.

Pramipexole dihydrochloride monohydrate 0.75 mg modified-release tablets:

White or nearly white, cylindrical and biconvex tablets marked with 052 on one side. AUST R 225621

Pramipexole dihydrochloride monohydrate 1.5 mg modified-release tablets:

White or nearly white, cylindrical and biconvex tablets marked with 105 on one side. AUST R 225580.

Pramipexole dihydrochloride monohydrate 2.25mg modified-release tablets:

White or nearly white, cylindrical and biconvex tablets marked with 157 on one side. AUST R 225586.

Pramipexole dihydrochloride monohydrate 3 mg modified-release tablets:

White or nearly white, cylindrical and biconvex tablets marked with 210 on one side. AUST R 225627.

Pramipexole dihydrochloride monohydrate 3.75mg modified-release tablets:

White or nearly white, cylindrical and biconvex tablets marked with 262 on one side. AUST R 225625.

Pramipexole dihydrochloride monohydrate 4.5 mg modified-release tablets:

White or nearly white, cylindrical, plans and bevel tablets marked with 315 on one side. AUST R 225597.

Available in blister packs 30 modified release tablets.

* Not all strengths may be available.

Ingredients

Each APO-Pramipexole ER modified release tablet contains either 0.375 mg, 0.75 mg, 1.5 mg, 2.25 mg, 3 mg, 3.75 mg or 4.5 mg of pramipexole dihydrochloride monohydrate. as the active ingredient.

It also contains the following:

- calcium hydrogen phosphate
- hypromellose
- magnesium stearate
- silicon dioxide

This medicine is free from gluten, lactose, sucrose, tartrazine and other azo dyes.

Sponsor

Arrotex Pharmaceuticals
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