

APO-PRAMIPEXOLE

Pramipexole hydrochloride

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 this medicine. 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 taking 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 need to read it again.

What this medicine is used for

Pramipexole is used in the treatment of 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. APO-PRAMIPEXOLE works by having a similar effect as dopamine in the brain.

APO-PRAMIPEXOLE contains the active ingredient Pramipexole hydrochloride. Pramipexole hydrochloride belongs to a group of medicines known as "dopamine agonists".

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

Your doctor may have prescribed it for another reason.

Before you take this medicine

When you must not take it

Only use this medicine if it has been prescribed for you by a doctor.

Never give it to someone else even if their symptoms seem to be the same as yours.

Do not take this medicine if you are allergic to pramipexole or any of the other ingredients in this medicine.

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 this medicine after the EXPIRY DATE on the carton or blister strips, or if the packaging is torn or damaged.

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
- heart problems
- blood pressure problems
- eye problems
- 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 him/her 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 this one may interfere with each other. These include:

- any medicines for the treatment of Restless Legs Syndrome
- 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)
- certain medicines used in the treatment of mental illness/ psychosis (antipsychotics or neuroleptics)
- metoclopramide - commonly used to help control nausea and vomiting
- cimetidine or ranitidine - used to treat stomach ulcer or reflux
- quinine - used to treat malaria
- some antibiotics (e.g. trimethoprim, cephalosporins, penicillins)
- indomethacin, a medicine used to treat arthritis
- chlorpropamide, a medicine used to treat diabetes
- medicines used to produce calmness or help you sleep e.g. sleeping tablets, sedatives or tranquillisers, and pain relievers
- other medicines that can cause drowsiness or sleepiness (e.g. antihistamine 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 avoid while taking this medicine.

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

Special care is recommended during pregnancy. The benefits of this medicine must be assessed against the possible effects on your unborn child.

This medicine is not recommended during breastfeeding.

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

In animal studies, this medicine was shown to pass into breast milk, and can stop the production of milk.

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

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.

A number of tablet strengths of this medicine are available (see Product Description below). Make sure that you only take the tablet strength that your doctor has prescribed.

Your doctor may reduce your daily dose if you have another medical condition such as a kidney problem, or if you are currently taking other medicines.

How much to take

The recommended initial dose for adults is one tablet 0.125 mg tablet three times per day. Your daily dose will be increased every week by your doctor until a suitable daily dose is reached. The maximum recommended daily dose for this medicine is 4.5 mg pramipexole hydrochloride.

Ask your doctor for more information if you have been advised to take a different dose to that referred to above.

How to take it

The tablets should be swallowed whole with a glass of water. This medicine can be taken with or without food.

If you forget to take it

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 try to make up for missed doses by taking more than one dose at a time.

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

If you take too much (overdose)

Immediately telephone your doctor, pharmacist or 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.

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

While you are using 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.

Do not stop taking this medicine or change the dose without checking with your doctor.

It is important not to suddenly stop taking this medicine, unless advised to do so by your doctor, since your condition may worsen.

If your doctor asks you to stop taking this medicine, the dose will normally need to be reduced gradually over several days.

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 to be careful of

Do not drive a car, operate machinery, or do anything else that could be dangerous (after taking this medicine) 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 this medicine 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 this medicine.

Combining this medicine 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 this medicine, 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.

Side effects

You should be aware that all prescription medicines carry some risks and that all possible risks may not be known at this stage despite thorough testing.

Your doctor has weighed the risks of your taking this medicine against the expected benefits.

Ask for the advice of your doctor or pharmacist if you have any concerns about the effects of taking this medicine.

The most common side effects of this medicine include nausea, constipation, drowsiness, hallucinations, confusion, dizziness and swelling of hands, ankles or feet (peripheral oedema). In patients also taking other medicines to treat Parkinson's disease, abnormal uncontrolled movements can occur.

These side effects tend to appear at the start of treatment and lessen or disappear with time.

Sudden onset of sleep episodes (while engaged in daily activities) have been reported with/without prior warning signs, such as excessive drowsiness.

Other reported side effects include hypersensitivity, diarrhoea, dry mouth, fatigue, visual disturbance including blurred vision and reduced visual acuity, vomiting, headache, light-headedness or low blood pressure (hypotension), trouble sleeping (insomnia), amnesia, restlessness, dream abnormalities, delusion, paranoia, weight gain, weight decrease.

Compulsive behaviour such as gambling, hypersexuality, shopping, eating, medication use and repetitive purposeless activities have been reported in patients taking dopamine agonists for the treatment of

Parkinson's disease, especially at high doses.

If you or your family notice an increase in compulsive behaviour, seek immediate medical advice. Your doctor may consider reducing or ceasing your treatment.

Tell your doctor as soon as possible if you experience any side effects during or after taking this medicine, so that these effects may be properly treated.

Other side effects not yet known or listed above, may also occur in some patients.

You should tell your doctor or pharmacist if you notice anything unusual, during or after taking this medicine.

Storage and Disposal

Storage

This medicine should be kept in a cool dry and dark place where the temperature stays below 30°C. Keep tablets in the packet until use to protect from light.

Do not store this medicine in direct sunlight or heat.

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

Keep your medicine where children cannot reach it.

Disposal

Return any unused medicine to your pharmacist so that it can be disposed of safely.

Product description

What it looks like

APO-PRAMIPEXOLE tablets are round and white for each strength.

APO-PRAMIPEXOLE 0.125 mg tablets are marked with an "A" on

one side of the tablet and are available in blister packs of 30 tablets. AUST R 227666

APO-PRAMIPEXOLE 0.25 mg tablets are marked with a "B" on one side of the tablet and are available in blister packs of 100 tablets. AUST R 227667

APO-PRAMIPEXOLE 1 mg tablets are marked with a "D" on one side of the tablet and are available in blister packs of 100 tablets. AUST R 227669

Ingredients

This medicine contains 0.125 mg, 0.25mg or 1 mg of pramipexole hydrochloride as the active ingredient.

This medicine also contains the following:

- mannitol
- pregelatinized maize starch
- microcrystalline cellulose
- povidone
- purified talc and
- magnesium stearate.

Sponsor

Southern Cross Pharma Pty Ltd
Suite 5/118 Church Street
Hawthorn VIC 3122
ABN 47 094 447 677

This leaflet was prepared in March 2018