APO-PRAMIPEXOLE ER

Contains the active ingredient pramipexole (as hydrochloride monohydrate)

Consumer Medicine Information

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about APO-Pramipexole ER tablets. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

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.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

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

What this medicine is used for

The name of your medicine is Pramipexole ER tablets. It contains the active ingredient pramipexole hydrochloride monohydrate.

It is used to treat symptoms 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 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 ER tablets works by having a similar effect as dopamine in the brain.

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.

How it works

Pramipexole hydrochloride monohydrate belongs to a group of medicines known as dopamine agonists, which bind to dopamine receptors.

There is no evidence that this medicine is addictive.

Use in children

This medicine not recommended for use in children under 18 years of age as its safety and effectiveness in that age group have not been established.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You are hypersensitive to, or have had an allergic reaction to, pramipexole hydrochloride monohydrate or any of the ingredients listed at the end of this leaflet.**
  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.
  If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.
- **The expiry date (EXP) printed on the pack has passed.**
- **The packaging is torn, shows signs of tampering or it does not look quite right.**

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
- any other medicines
- any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
- kidney problems
- mental illnesses
- low blood pressure
- trouble controlling your muscles (dyskinesia).
3. You are currently pregnant, or likely to become pregnant during your course of medication. Your doctor can discuss with you the benefits and risks of taking this medicine.
4. You are currently breastfeeding, or likely to breast-feed during your course of medication. This medicine is not recommended during breastfeeding, as it may pass into breast milk.
5. You are planning to have surgery or an anaesthetic.
6. You are currently receiving or are planning to receive dental treatment.
7. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Taking other medicines

Some medicines may interact with pramipexole hydrochloride monohydrate. 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
- metoclopramide, a medicine used to treat nausea and vomiting
- some medicines used to treat stomach or duodenal ulcers (e.g. cimetidine or ranitidine)
- quinine, a medicine 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).

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with Pramipexole ER tablets.

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

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

The usual dose is one tablet a day.

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

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

If you are switching from the immediate-release Pramipexole tablets:
Your doctor will base your dose of Pramipexole ER tablets on the dose of the immediate-release Pramipexole tablets you were taking.

Take your immediate-release Pramipexole tablets as normal the day before you switch. Then take your Pramipexole ER tablets the next morning and do not take any more of the immediate-release Pramipexole tablets.

How to take it

Swallow the tablet whole with a full glass of water.

Do not chew, divide or crush Pramipexole ER.

When to take it

Take Pramipexole ER 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.

Pramipexole tablets can be taken with or without food.

How long to take it for

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

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

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for missed doses.
This may increase the chance of you experiencing side effects.

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

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much Pramipexole ER you may have nausea, vomiting, abnormal uncontrolled movements, hallucinations, agitation and dizziness or light-headedness.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

Be careful when 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.

Be careful when drinking alcohol while taking Pramipexole ER.

Combining Pramipexole ER and alcohol can make you more drowsy or sleepy.

Be careful getting up from a sitting or lying position.

You may feel dizzy or light-headed while taking Pramipexole ER, 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.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking Pramipexole ER or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

- 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.

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

These may be serious side effects and you may need medical attention:

- loss of memory (amnesia)
- fainting
- 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).

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

Allergic reactions

If you think you are having an allergic reaction to pramipexole ER, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, 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
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay 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 this 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.

Disposal

If your doctor tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Pramipexole ER Dosage Form looks like

Pramipexole hydrochloride monohydrate 0.375 mg modified release tablets:
White or nearly white, cylindrical, plans and bevel tablets marked with 026 on one side.

Pramipexole hydrochloride monohydrate 0.75 mg modified release tablets:
White or nearly white, cylindrical and biconvex tablets marked with 052 on one side.

Pramipexole hydrochloride monohydrate 1.5 mg modified release tablets:
White or nearly white, cylindrical and biconvex tablets marked with 105 on one side.

Pramipexole hydrochloride monohydrate 2.25 mg modified release tablets:
White or nearly white, cylindrical and biconvex tablets marked with 157 on one side.

Pramipexole hydrochloride monohydrate 3 mg modified release tablets:
White or nearly white, cylindrical and biconvex tablets marked with 210 on one side.

Pramipexole hydrochloride monohydrate 3.75 mg modified release tablets:
White or nearly white, cylindrical and biconvex tablets marked with 262 on one side.

Pramipexole hydrochloride monohydrate 4.5 mg modified release tablets:
White or nearly white, cylindrical, plans and bevel tablets marked with 315 on one side.

Ingredients

Each tablet contains: 0.375 mg/ 0.75 mg/ 1.5 mg/ 2.25 mg/ 3 mg/ 3.75 mg/ 4.5 mg of pramipexole as the active ingredient.

It also contains the following inactive ingredients:

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

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

Australian Registration Numbers

Pramipexole hydrochloride monohydrate 0.375 mg modified release tablets. (PA/Al/PVC/Al - polyamide-aluminium foil-polyvinylchloride/aluminium foil). (AUST R 225622).

Pramipexole hydrochloride monohydrate 0.75 mg modified release tablets. (PA/Al/PVC/Al - polyamide-aluminium foil-polyvinylchloride/aluminium foil). (AUST R 225621).

Pramipexole hydrochloride monohydrate 1.5 mg modified release tablets. (PA/Al/PVC/Al - polyamide-aluminium foil-polyvinylchloride/aluminium foil). (AUST R 225580).

Pramipexole hydrochloride monohydrate 2.25 mg modified release tablets. (PA/Al/PVC/Al - polyamide-aluminium foil-polyvinylchloride/aluminium foil). (AUST R 225586).

Pramipexole hydrochloride monohydrate 3 mg modified release tablets. (PA/Al/PVC/Al - polyamide-aluminium foil-polyvinylchloride/aluminium foil). (AUST R 225627).

Pramipexole hydrochloride monohydrate 3.75 mg modified release tablets. (PA/Al/PVC/Al - polyamide-aluminium foil-polyvinylchloride/aluminium foil). (AUST R 225625).

Pramipexole hydrochloride monohydrate 4.5 mg modified release tablets. (PA/Al/PVC/Al - polyamide-aluminium foil-polyvinylchloride/aluminium foil). (AUST R 225597).

Available in blister packs of 10 and 30 modified release tablets.

* Not all strengths, pack types and/or pack sizes may be available.

Sponsor

Generic Partners Pty Ltd
Suite 3 191 Riversdale Road
HAWTHORN VIC 3122
Australia

Distributor

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113

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