PRAMIPEXOLE XR GP

contains the active ingredient pramipexole hydrochloride monohydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about PRAMIPEXOLE XR GP.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking PRAMIPEXOLE XR GP against the benefits it is expected to have for you.

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

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

What this medicine is used for

PRAMIPEXOLE XR GP is used to treat the 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.

How it works

PRAMIPEXOLE XR GP contains the active ingredient pramipexole hydrochloride monohydrate, which belongs to a group of medicines known as dopamine agonists, which bind to dopamine receptors.

PRAMIPEXOLE XR GP works by having a similar effect as dopamine in the brain.

Ask your doctor if you have any questions about why PRAMIPEXOLE XR GP has been prescribed for you.
Your doctor may have prescribed PRAMIPEXOLE XR GP for another reason.

PRAMIPEXOLE XR GP is not addictive.

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

Before you take this medicine

When you must not take it

Do not have PRAMIPEXOLE XR GP if you have an allergy to:

- Any medicine containing pramipexole hydrochloride monohydrate
- 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 or other parts of the body
- skin rash, itching or hives

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 use PRAMIPEXOLE XR GP after the expiry date (EXP) printed on the pack or if the packaging is torn or shows signs of tampering.

If you are not sure whether you should use PRAMIPEXOLE XR GP, talk to your doctor or pharmacist.

Before you start to use 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 likely to become pregnant during your course of medication.
Your doctor can discuss with you the benefits and risks PRAMIPEXOLE XR GP involved.

Tell your doctor if you are breastfeeding, or likely to breastfeed during your course of medication.
PRAMIPEXOLE XR GP 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 or pharmacist about any of the above, tell them before you start taking PRAMIPEXOLE XR GP.

Taking other medicines

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

Some medicines and PRAMIPEXOLE XR GP 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
- 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)

These medicines may be affected by PRAMIPEXOLE XR GP 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 and pharmacist may have more information on medicines to be careful with or to avoid while taking PRAMIPEXOLE XR GP.

How to take it

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

Pramipexole XR GP 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 label, ask your doctor or pharmacist for help.

How much to take

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.If you are switching from the immediate-release pramipexole tablets:

Your doctor will base your dose of PRAMIPEXOLE XR GP 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 modified release PRAMIPEXOLE XR GP 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 XR GP modified release tablets.

PRAMIPEXOLE XR GP tablets can be taken with or without food.

When to take it

Take PRAMIPEXOLE XR GP 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 PRAMIPEXOLE XR GP 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

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.

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

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

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

If you take too much PRAMIPEXOLE XR GP 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 all doctors and pharmacists who are treating you that you are taking PRAMIPEXOLE XR GP.

If you feel that PRAMIPEXOLE XR GP is not helping your condition, tell your doctor or pharmacist.

Tell your doctor if, for any reason, you have not used PRAMIPEXOLE XR GP 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 XR GP 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 XR GP 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. For example, you may experience abnormal posture such as forward bending of the head and neck, forward bending of the lower back or sidewards bending of the back.

Things you must not do

Do not give PRAMIPEXOLE XR GP to anyone else, even if they have the same condition as you.

Do not stop taking PRAMIPEXOLE XR GP or change the dose without checking with your doctor.
It is important not to suddenly stop taking your PRAMIPEXOLE XR GP tablets, unless advised to do so by your doctor, since your condition may worsen.

If your doctor asks you to stop taking PRAMIPEXOLE XR GP, 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 PRAMIPEXOLE XR GP 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 XR GP 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 XR GP.
Combining PRAMIPEXOLE XR GP 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 XR GP, 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 XR GP.

PRAMIPEXOLE XR GP 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 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
- Forward bending of the head and neck.

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

After using this medicine

Storage

Keep PRAMIPEXOLE XR GP in the pack until it is time to take it.

Keep PRAMIPEXOLE XR GP in a cool dry place where the temperature stays below 25°C.

Do not store PRAMIPEXOLE XR GP or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep your PRAMIPEXOLE XR GP where young 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 it looks like

PRAMIPEXOLE XR GP are modified release tablets, and are available in seven strengths: 0.375 mg, 0.75 mg, 1.5 mg, 2.25 mg, 3 mg, 3.75 mg and 4.5 mg.

- PRAMIPEXOLE XR GP 0.375 mg modified release tablets are white or nearly white, cylindrical, plans and bevel tablets marked with 026 on one side.

- PRAMIPEXOLE XR GP 0.75 mg modified release tablets are white or nearly white, cylindrical and biconvex tablets marked with 052 on one side.
- PRAMIPEXOLE XR GP 1.5 mg modified release tablets are white or nearly white, cylindrical and biconvex tablets marked with 105 on one side.
- PRAMIPEXOLE XR GP 2.25mg modified release tablets are white or nearly white, cylindrical and biconvex tablets marked with 157 on one side.
- PRAMIPEXOLE XR GP 3 mg modified release tablets are white or nearly white, cylindrical and biconvex tablets marked with 210 on one side.
- PRAMIPEXOLE XR GP 3.75mg modified release tablets are white or nearly white, cylindrical and biconvex tablets marked with 262 on one side.
- PRAMIPEXOLE XR GP 4.5 mg modified release tablets are white or nearly white, cylindrical, plans and bevel tablets marked with 315 on one side.

PRAMIPEXOLE XR GP are available in blister packs of 30 modified release tablets.

Ingredients

- Each PRAMIPEXOLE XR GP 0.375 mg modified release tablet contains 0.375 mg pramipexole hydrochloride monohydrate.
- Each PRAMIPEXOLE XR GP 0.75 mg modified release tablet contains 0.75 mg pramipexole hydrochloride monohydrate.
- Each P PRAMIPEXOLE XR GP 1.5 mg modified release tablet contains 1.5 mg pramipexole hydrochloride monohydrate.
- Each PRAMIPEXOLE XR GP 2.25 mg modified release tablet contains 2.25 mg pramipexole hydrochloride monohydrate.
- Each PRAMIPEXOLE XR GP 3 mg modified release tablet contains 3 mg pramipexole hydrochloride monohydrate.
- Each PRAMIPEXOLE XR GP 3.75 mg modified release tablet contains 3.75 mg pramipexole hydrochloride monohydrate.
- Each PRAMIPEXOLE XR GP 4.5 mg modified release tablet contains 4.5 mg pramipexole hydrochloride monohydrate.

Each PRAMIPEXOLE XR GP tablet also contains the following inactive ingredients:

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

PRAMIPEXOLE XR GP does not contain lactose, gluten, tartrazine or any other azo dyes.

Supplier

Alphapharm Pty Limited
Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.mylan.com.au

Australian Registration Numbers:

PRAMIPEXOLE XR GP 0.375 mg modified release tablets:

AUST R 225591

PRAMIPEXOLE XR GP 0.75 mg modified release tablets:

AUST R 225585

PRAMIPEXOLE XR GP 1.5 mg modified release tablets:

AUST R 225600

PRAMIPEXOLE XR GP 2.25mg modified release tablets:

AUST R 225588

PRAMIPEXOLE XR GP 3 mg modified release tablets:

AUST R 225631

PRAMIPEXOLE XR GP 3.75mg modified release tablets:

AUST R 225599

PRAMIPEXOLE XR GP 4.5 mg modified release tablets:

AUST R 225617

Date of preparation

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