PRAMIPEXOLE AN

Pramipexole hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about PRAMIPEXOLE AN. It does not contain all available information, nor does it take place of talking to your doctor or pharmacist.

Keep this information with your PRAMIPEXOLE AN.
You may need to read it again later.

To find out more about PRAMIPEXOLE AN:

You should ask your doctor or pharmacist if you have any questions about PRAMIPEXOLE AN or if you have any trouble before, during or after using PRAMIPEXOLE AN.

1. What PRAMIPEXOLE AN is used for

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

PRAMIPEXOLE AN 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 PRAMIPEXOLE AN has been prescribed for you.

Your doctor may have prescribed PRAMIPEXOLE AN for another reason.

2. Before you take it

2a) When you must not take it

Only use PRAMIPEXOLE AN 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 PRAMIPEXOLE AN if you are allergic to pramipexole or any of the other ingredients in PRAMIPEXOLE AN.

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

2b) Before you start to take it

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

Before taking PRAMIPEXOLE AN, you must tell your doctor if you have, or have had, any of the following 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.

Before using PRAMIPEXOLE AN, it is important to tell your doctor if you are taking any other medicines, obtained with or without a doctor's prescription.

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

- 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 PRAMIPEXOLE AN 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.

2c) Pregnancy

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 PRAMIPEXOLE AN must be assessed against the possible effects on your unborn child.

2d) Breastfeeding

PRAMIPEXOLE AN 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, PRAMIPEXOLE AN was shown to pass into breast milk, and can stop the production of milk.

2e) Children

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

3. Taking PRAMIPEXOLE AN

3a) How to take PRAMIPEXOLE AN

It is important to take your PRAMIPEXOLE AN tablets as directed by your doctor.

A number of tablet strengths of PRAMIPEXOLE AN are available (see section 7, Product description). 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.

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

The recommended initial dose for adults is one PRAMIPEXOLE AN 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 PRAMIPEXOLE AN 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.

3b) If you forget to take a dose

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.

3c) If you have taken too much PRAMIPEXOLE AN (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 AN.

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.

4. While you are taking it

4a) Things you must do

Tell all doctors and pharmacists who are treating you that you are taking PRAMIPEXOLE AN.

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

If your doctor asks you to stop taking PRAMIPEXOLE AN, 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.

4b) Things to be careful of

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

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

Make sure you know how you react to PRAMIPEXOLE AN 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 AN. Combining PRAMIPEXOLE AN 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 AN, 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.

5. 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 PRAMIPEXOLE AN against the expected benefits.

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

The most common side effects of PRAMIPEXOLE AN 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, lightheadedness 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 PRAMIPEXOLE AN, 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 PRAMIPEXOLE AN.

6. After taking it

6a) Storage

PRAMIPEXOLE AN 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 your PRAMIPEXOLE AN in direct sunlight or heat.
For example, do not leave your PRAMIPEXOLE AN in the car on hot days.

Keep your PRAMIPEXOLE AN where children cannot reach it.

6b) Disposal

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

7. Product description

PRAMIPEXOLE AN is the brand name of your medicine.

PRAMIPEXOLE AN tablets are round and white for each strength.

- PRAMIPEXOLE AN 0.125 mg tablets are marked with an "A" on one side of the tablet and are available in blister packs of 30 tablets.
- PRAMIPEXOLE AN 0.25 mg tablets are marked with a "B" on one side of the tablet and are available in blister packs of 100 tablets.
- PRAMIPEXOLE AN 1 mg tablets are marked with a "D" on one side of the tablet and are available in blister packs of 100 tablets.
- PRAMIPEXOLE AN tablets 0.5 (marked with a "C" on one side of the tablet) and 1.5 mg tablets (marked with an "E" on one side of the tablet) are not currently marketed in Australia.

The following Australian Registration Numbers appear on the carton:

- PRAMIPEXOLE AN 0.125 mg tablets AUST R 172009
- PRAMIPEXOLE AN 0.25 mg tablets AUST R 172012
- PRAMIPEXOLE AN 1 mg tablets AUST R 172014

Ingredients

- Each PRAMIPEXOLE AN 0.125 mg tablet contains pramipexole hydrochloride 0.125 mg.
- Each PRAMIPEXOLE AN 0.25 mg tablet contains pramipexole hydrochloride 0.25 mg.
- Each PRAMIPEXOLE AN 1 mg tablet contains pramipexole hydrochloride 1 mg.

The other ingredients found in all strengths are:

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

Sponsor

Southern Cross Pharma Pty Ltd
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