

## PRAMIPEXOLE GH

*pramipexole dihydrochloride monohydrate*

### **What is in this leaflet**

This leaflet answers some common questions about PRAMIPEXOLE GH. It does not contain all the information and does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risk of you taking PRAMIPEXOLE GH against the benefits they expect it will have for you.

**Talk to your doctor or pharmacist if you have any concerns about taking this medicine.**

**Keep this leaflet with the medicine.**

You may need to read it again.

### **What PRAMIPEXOLE GH is used for**

PRAMIPEXOLE GH 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 GH works by having a similar effect as dopamine in the brain. PRAMIPEXOLE GH 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 GH has been prescribed for you.**

Your doctor may have prescribed PRAMIPEXOLE GH for another reason.

### **Before you take PRAMIPEXOLE GH**

#### ***When not to take it***

**Only use PRAMIPEXOLE GH 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 GH if you are allergic to pramipexole or any of the other ingredients listed at the end of this leaflet.**

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

#### ***Before you start to take it***

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

Before taking this medicine, 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 GH, 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 (eg 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 (eg antihistamine or some cough and cold preparations)

These medicines may be affected by PRAMIPEXOLE GH 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.

**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 GH must be assessed against the possible effects on your unborn child.

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

**Use in Children**

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

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**How to take PRAMIPEXOLE GH**

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

A number of tablet strengths are available (see 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.

**How much to take**

The recommended initial dose for adults is one PRAMIPEXOLE GH 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 GH 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. PRAMIPEXOLE GH can be taken with or without food.

**If you take too much**

**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 GH.**

**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.

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## **While you are taking PRAMIPEXOLE GH**

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### ***Things you must do***

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

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

If your doctor asks you to stop taking PRAMIPEXOLE GH, 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.**

**Seek immediate medical advice if you or your family notices an increase in compulsive behaviour.**

### ***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.**

### ***Things to be careful of***

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

**It may cause drowsiness, hallucinations and episodes of sudden onset of sleep, in some people.**

**Make sure you know how you react to it 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 GH. Combining it 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 GH, 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.

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## **Side Effects**

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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 GH against the expected benefits.

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

The most common side effects of PRAMIPEXOLE GH 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 GH, 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 GH.

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## **How to store PRAMIPEXOLE GH**

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### **Storage**

**PRAMIPEXOLE GH should be kept in a cool dry and dark place where the temperature stays below 25°C. Keep tablets in the packet until used, to protect from light.**

**Do not store your PRAMIPEXOLE GH in direct sunlight or heat.**

For example, do not leave your PRAMIPEXOLE GH 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.

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## **Product description**

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### **What PRAMIPEXOLE GH tablets look like**

PRAMIPEXOLE GH tablets are round and white for each strength.

PRAMIPEXOLE GH 0.125 mg tablets are debossed with 'CL' on one side of the tablet and '2' on the other side.

PRAMIPEXOLE GH 0.25 mg tablets are with 'CL' and '3' debossed on one side of the tablet with breakline separating 'CL' and '3' and having a breakline on the other side.

PRAMIPEXOLE GH 0.5\* mg tablets are with 'CL' and '4' debossed on one side of the tablet with breakline separating 'CL' and '4' and having a breakline on the other side.

PRAMIPEXOLE GH 1 mg tablets are with 'CL' and '5' debossed on one side of the tablet with breakline separating 'CL' and '5' and having a breakline on the other side.

PRAMIPEXOLE GH 1.5\* mg tablets are with 'CL' and '6' debossed on one side of the tablet with breakline separating 'CL' and '6' and having a breakline on the other side.

Presented in Al/Al blister packs of 10's, 30's and 100's tablets.

\*Not all strengths or pack sizes may be available.

### **Ingredients**

Each PRAMIPEXOLE GH tablet contains the following amount of active ingredient:

- 0.125 mg tablet contains 0.125 mg of pramipexole hydrochloride.
- 0.25 mg tablet contains 0.25 mg of pramipexole hydrochloride.
- 0.5 mg tablet contains 0.5 mg of pramipexole hydrochloride.
- 1 mg tablet contains 1 mg of pramipexole hydrochloride.
- 1.5 mg tablet contains 1.5 mg of pramipexole hydrochloride.

The other ingredients found in all strengths are:

- mannitol,
- pregelatinized maize starch
- povidone,
- colloidal anhydrous silica
- magnesium stearate

### **Sponsor**

Generic Health Pty Ltd

Level 1, 1102 Toorak Road  
Camberwell, VIC, 3124

***Australian Registration  
Numbers***

PRAMIPEXOLE GH 0.125  
mg  
- AUST R 214463  
PRAMIPEXOLE GH 0.25 mg  
- AUST R 214456  
PRAMIPEXOLE GH 0.5 mg -  
AUST R 214438  
PRAMIPEXOLE GH 1 mg -  
AUST R 214453  
PRAMIPEXOLE GH 1.5 mg -  
AUST R 214454

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