

# PRAMEXOL TABLET

pramipexole dihydrochloride monohydrate (0.125mg, 0.25mg, 1mg) is equivalent to (0.088mg, 0.18mg, 0.7mg) of pramipexole

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## What Pramexol is used for

Treat the symptoms of primary Parkinson's disease<sup>1</sup> in adults. It can be used alone or in combination with Levodopa (another medicine for Parkinson's disease). Also, to treat idiopathic Restless Legs Syndrome (a common condition of the nervous system that causes an overwhelming, irresistible urge to move the legs).

## How Pramexol works

Pramexol contains the active substance Pramipexole. Pramipexole belongs to a group of medicines known as dopamine agonists, which stimulates dopamine receptors in the brain. Stimulation of the dopamine receptors triggers nerve impulses in the brain that help to control body movements.

## Before you use Pramexol

### - When you must not use it

- ⊗ If you are allergic (hypersensitive) to Pramipexole or any of the other ingredients of this medicine (listed in *Ingredients*).
- ⊗ Pramexol is not recommended for use in children or adolescents under 18 years.

### Pregnancy and breastfeeding

- ⊗ Do not take Pramexol if you are pregnant, trying to get pregnant or think you may be pregnant.
- ⊗ Do not take Pramexol if you are breastfeeding. Ask your doctor or pharmacist for advice before taking any medicine.

### - Before you start to use it

Talk to your doctor or pharmacist before taking Pramexol. Tell your doctor if you have (had) or develop any medical conditions or symptoms, especially any of the following:

- If you have kidney disease.
- If you experience hallucinations (seeing, hearing or feeling things that are not there).
- If you have dyskinesia (e.g. abnormal, uncontrolled movement of the limbs). If you have advanced Parkinson's disease and are also taking Levodopa, you might develop dyskinesia during the up-titration of Pramexol.
- If you have sleepiness and episodes of suddenly falling asleep.
- If you have psychosis (e.g. comparable with symptoms of schizophrenia such as withdrawal from reality, illogical patterns of thinking, delusions and hallucinations.)
- If you have vision impairment.
- If you have severe heart or blood vessels disease.
- If you have augmentation. You may experience that symptoms start earlier than usual, be more intense and involve other limbs.

### - Taking other medicines

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

Especially, if you are taking:

- Cimetidine (to treat excess stomach acid and stomach ulcers);
- Amantadine (which can be used to treat Parkinson's disease);
- Mexiletine (to treat irregular heartbeats);
- Zidovudine (to treat HIV);
- Cisplatin (to treat cancers);
- Quinine (to treat malaria);
- Any antipsychotic medicine;
- Levodopa (to treat Parkinson's disease), the dose of Levodopa is recommended to be reduced when you start treatment with Pramexol.

## How to use Pramexol

### - How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

### Parkinson's disease

The daily dose is to be taken divided into 3 equal doses.

During the first week, the usual dose is 0.375 mg per day and increased every 5-7 days as directed by your doctor until you symptoms are controlled (maintenance dose).

Ascending dose schedule of Pramipexole		
Week	Dosage (mg)	Total daily dose (mg)
1	3 x 0.125	0.375
2	3 x 0.25	0.75
3	3 x 0.5	1.50

### Maintenance treatment

The individual dose should be in the range of 0.375 mg to a maximum of 4.5 mg per day.

### Restless Legs Syndrome

The recommended starting dose of Pramexol is 0.125 mg taken once daily 2-3 hours before bedtime. For patients requiring additional symptomatic relief, the dose may be increased every 4-7 days to a maximum of 0.75 mg per day (as shown in the table below):

Ascending dose schedule of Pramipexole	
Week	Total Daily Dose (mg of base)
1	0.125
2*	0.25
3*	1.50
4*	0.75

\*if needed

### - When to use it

Use as directed by your doctor or pharmacist.

### - How long to use it

Continue taking Pramexol for as long as your doctor recommends.

### - If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take double dose to make up for the missed dose.

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## - If you use too much (overdose)

Contact your doctor or immediately or go the Emergency Department of your nearest hospital, if you think 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.

Taking too many tablets may cause nausea, vomiting, muscle spasm, hallucination, agitation, and low blood pressure.

## **While you are using it**

### - Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Pramexol.

Tell your doctor immediately if you become pregnant while taking this medication.

### - Things you must not do

Do not stop taking Pramexol without first talking to your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Pramexol to anyone else, even if they have the same symptoms or condition as you.

### - Things to be careful of

#### Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

## **Side effects**

Like all medicines, Pramexol can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Very common side effects include:

- dizziness
- sleepiness
- dyskinesia (abnormal, uncontrolled movement of the limbs)

Common side effects:

- insomnia
- hallucinations
- abnormal dreams

- confusions
- impulse control disorders (e.g. increased gambling, libido, hypersexuality, compulsive spending or buying, binge and compulsive eating)
- headache
- visual impairment
- blurred or reduced visual
- low blood pressure
- constipation
- vomiting
- tiredness
- peripheral edema (accumulation of excessive amounts of fluid especially in hands and legs)
- weight decrease including decreased appetite

Uncommon side effects:

- lung infection
- inappropriate hormone secretion
- compulsive shopping
- increased gambling
- restlessness
- hypersexuality
- delusion
- libido disorder
- paranoia
- binge eating
- delirium
- sudden onset of sleep
- amnesia (loss or impairment of memory)
- muscle spasm
- sudden loss of consciousness
- heart failure
- allergic, itchiness, rash
- increased weight
- difficulty in breathing
- vomiting

Other side effects:

- mania (mental illness marked by periods of great excitement or euphoria, delusions and overactivity)
- anxiety
- depression
- sweating
- pain
- lack of interest, enthusiasm, or concern

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website <http://www.npra.gov.my> [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

## **Storage and Disposal of Pramexol**

### Storage

Keep medicines out of reach of children.

Store at temperature of not more than 30°C.

### Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will protect the environment.

## **Product Description**

### - What it looks like?

#### **0.125 mg:**

White, flat, round tablet with engraved PM on one side and plain on the other

#### **0.25 mg:**

White, oval, flat-faced tablet with bevelled edge, engraved PM on one side and scored on the other

#### **1 mg:**

White, round, flat-faced tablet with bevelled edge, engraved PM1 on one side and cross-scored on the other

### - Ingredients

- Active ingredient:

*Pramipexole dihydrochloride monohydrate (0.125, 0.25 mg and 1 mg) eq. to Pramipexole base (0.088 mg, 0.18 mg and 0.7 mg)*

- Inactive ingredients:  
*Microcrystalline cellulose (Avicel PH 101), Corn starch, Croscarmellose sodium, Calcium carbonate heavy, Mannitol, Povidone (PVP K-30), Edetate disodium, Sodium metabisulfite, Purified water, Colloidal silicon dioxide (Aerosil 200), and Magnesium stearate*

### - MAL Number:

**PRAMEXOL 0.125mg Tablet:**  
MAL\*\*\*\*\*

**PRAMEXOL 0.25mg Tablet:**  
MAL23016007AZ

**PRAMEXOL 1 Tablet:**  
MAL19126013AZ

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**Manufacturer**

Unison Laboratories Co., Ltd.  
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Muang Chachoengsao,  
Chachoengsao 24000 Thailand

**Product Registration Holder**

MEDISPEC (M) SDN. BHD.  
No. 55 & 57, Lorong Sempadan 2  
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**Date of Revision**

24/04/2024

**Serial number**

NPRA (R2) 22/153