

PRAMISON (Pramipexole Tablets 0.125 mg)

PRAMISON (Pramipexole Tablets 0.25 mg)

PRAMISON (Pramipexole Tablets 1 mg)

Pramipexole Dihydrochloride Monohydrate (0.125mg, 0.25mg and 1mg)

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What PRAMISON is used for

PRAMISON used to treat the sign and symptoms of advanced idiopathic parkinson's disease in adults. It can be used alone or in combination with levodopa (another medicine for Parkinson's disease). PRAMISON is also used to treat the symptoms of idiopathic Restless Legs Syndrome.

How PRAMISON works

PRAMISON contains the active ingredient Pramipexole which is a highly selective dopamine receptor activator in the brain. PRAMISON alleviates parkinsonian motor deficits by stimulation of dopamine receptors in the brain. Pramipexole protect dopamine neurons from degeneration in response to low oxygen or methamphetamine neurotoxicity.

Before you use PRAMISON

-When you must not use it

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Your doctor will then discuss with you if you should continue to take PRAMISON. The effect of PRAMISON on the unborn child is not known. Therefore, do not take PRAMISON if

you are pregnant unless your doctor tells you to do so. PRAMISON should not be used during breastfeeding. PRAMISON can reduce the production of breast milk. Also, it can pass into the breast milk and can reach your baby. If use of PRAMISON is unavoidable, breast-feeding should be stopped.

- Before you start use it

Do not take PRAMISON if you are allergic to pramipexole or to any of the other ingredients of this medicine.

Warning and precaution for use

PRAMISON has been associated with somnolence and episodes of sudden onset, particularly in patients with Parkinson's diseases. Sudden onset of sleep during daily activities, in some cases without awareness or warning signs, has been reported very rarely. Patients must be informed of this and advised to exercise caution while driving or operating machines during treatment with PRAMISON.

Patients who have experienced somnolence and/or an episode of sudden sleep onset must refrain from driving or operating machines. Furthermore a reduction of dosage or termination of therapy may be considered.

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines, herbal remedies, health foods or supplements that you have obtained without a prescription. You should avoid taking PRAMISON together with antipsychotic medicines. Tell your doctor if you are particular taking the following medicines:

- cimetidine (to treat excess stomach acid and stomach ulcers);

- amantadine (used to treat Parkinson's disease);
- mexiletine (to treat irregular heartbeats, a condition known as ventricular arrhythmia);
- Zidovudine (To treat HIV)
- Cisplatin (Anti- cancer)
- Quinine (To treat malaria)
- Procainamide (To treat cardiac problem)

If you are taking levodopa, the dose of levodopa is recommended to be reduced when you start treatment with PRAMISON.

Take care if you are using any medicines that calm you down (have a sedative effect) or if you are drinking alcohol. In these cases, PRAMISON may affect your ability to drive and operate machinery.

How to use PRAMISON

How much to use

Always take this medicine exactly as your doctor has told you. The doctor will advise you on the right dosing.

The tablet should be taken orally, swallowed with water, and can be taken either with or without food.

Parkinson's disease

The daily dosage is administrated in equally divided doses 3 times per day.

Initial Treatment:

As shown below dosages should be increased gradually from a starting-dose of 0.375 mg per day and then increased every 5 - 7 days. Providing patients do not experience intolerable side-effects, the dosage should be titrated to achieve a maximal therapeutic effect.

Ascending – Dose Schedule of Pramison		
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

If a further dose increase is necessary, the daily dose should be increased by 0.75 mg at weekly intervals up to a maximum dose of 4.5 mg daily.

Maintenance Treatment:

The individual dose of pramipexole should be in the range of 0.375 mg to a maximum of 4.5 mg per day. During dose escalation in pivotal studies both, in early and advanced disease efficacy was observed starting at a daily dose of 1.5 mg. This does not preclude that in individual patients doses higher than 1.5mg per day can result in additional therapeutic benefit.

This applies particularly to patients with advanced disease where a reduction of the levodopa therapy is intended

Restless Legs Syndrome

The recommended starting dose of Pramison 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	
Titration Step	Once Daily Evening Dose (mg of salt)
1	0.125
2*	0.25
3*	0.50
4*	0.75
* if needed	

Dosing in Children and Adolescent

Safety and efficacy of Pramison have not been established in children and adolescents up to 18 years.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking PRAMISON 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 a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to 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.

You may experience vomiting, restlessness, hypotension or any of the side effects.

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 PRAMISON.

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

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

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

- Things to be careful of

Driving and using machines

PRAMISON can cause hallucinations (seeing, hearing or feeling things that are not there). If affected, do not drive or use machines. PRAMISON has been associated with sleepiness and episodes of suddenly falling asleep, particularly in patients with Parkinson's disease. If you experience these side effects, you must not drive or operate machinery. You should tell your doctor if this occurs.

Side effects

Expected adverse effects

The following adverse reaction are expected under the use of Pramipexole:

- Abnormal Dream
- Amnesia
- Behavioral symptoms of impulse control disorder
- Compulsion such as binge eating, compulsive shopping, hyper sexuality, pathological gambling, cardiac failure, confusion, constipation, breathing difficulties, fatigue, headache, delusion, dizziness, libido disorders, nausea, paranoia, and other hypersensitivity; restlessness, somnolence, sudden onset of sleep, syncope, visual impairment.

The most commonly reported adverse reactions in patients with Parkinson's disease more frequent with pramipexole treatment as listed below:

Very common:

- **Nervous system disorder.**
Dizziness, headache, somnolence
- **Gastrointestinal Disorder**
Nausea

Common side effect:

- **Psychiatric disorder**
Confusion and hallucination
- **Nervous system disorder.**
Headache
- **Gastrointestinal Disorder**
Constipation, hiccups
- **General disorders and administration site conditions**
Fatigue, peripheral edema.
- **Investigations**

Weight decrease including decreased appetite.

- **Eye disorders**

Double vision, Blurred vision, vision clarity reduced.

Serious side effect:

- **Infections & infestations**

Lungs infection

- **Endocrine disorders**

Inappropriate endocrine hormone secretion

You may report any side effects or adverse drug reactions directly to The National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.moh.gov.my (Consumers -> Reporting -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of PRAMISON

- Storage

- Keep out of the reach and sight of children.
- Do not Store above 30°C.
- Protect from light

- 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 help to protect the environment.

Product Description

- What it looks like

Pramipexole Tablets 0.125 mg:

White to off-white, round, flat, beveled edge uncoated tablets, debossed with 'Y' on one side '41' on the other side. There is no score line and the dimension of the tablet is 1.60 mm - 2.20 mm.

Pramipexole Tablets 0.25 mg:

White to off-white, oval, biconcave, beveled edge uncoated tablets, debossed with 'Y' and '42' separated by score line on one side and plain with score line on other side and

dimension of the tablet is 6.5mm x 4.5mm.

Pramipexole Tablets 1 mg:

White to off-white, round, flat, beveled edge uncoated tablets debossed with 'Y' and '45' separated by score line on one side and plain with score line on other side and dimension of the tablet is 9.3mm.

- Ingredients

- Active ingredient(s)

Pramipexole Dihydrochloride Monohydrate

- Inactive ingredients

Mannitol, Maize starch, Povidone, Silica colloidal anhydrous and Magnesium Stearate.

- MAL number(s):

PRAMISON (Pramipexole Tablets 0.125 mg):

MAL 18116133AZ

PRAMISON (Pramipexole Tablets 0.25 mg):

MAL 18116132AZ

PRAMISON (Pramipexole Tablets 1 mg):

MAL 18116131AZ

Manufacturer

Aurobindo Pharma Limited, Unit-VII (SEZ)

Survey No. 411/P, 425/P, 434/P, 435/P & 458/P, Plot No. S1 (Part) Special Economic Zone (Pharma), TSIIC, Green Industrial Park, Polepally Village, Jedcheria Mandal, Mahaboobnagar District, Telangana State 509 302 INDIA

Product Registration Holder UNIMED SDN BHD

No. 53, Jalan Tembaga SD 5/2B, Bandar Sri Damansara, 52200, Kuala Lumpur, Malaysia.

Date of revision

21/02/2020

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