

Package leaflet: Information for the patient

Pramipexole Mylan 0.088 mg tablets

Pramipexole Mylan 0.18 mg tablets

Pramipexole Mylan 0.7 mg tablets

pramipexole

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Pramipexole Mylan is and what it is used for
2. What you need to know before you take Pramipexole Mylan
3. How to take Pramipexole Mylan
4. Possible side effects
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1. What Pramipexole Mylan is and what it is used for

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

Pramipexole Mylan is used to:

- treat the symptoms of primary Parkinson's disease in adults. It can be used alone or in combination with levodopa (another medicine for Parkinson's disease).

2. What you need to know before you take Pramipexole Mylan

Do not take Pramipexole Mylan:

- if you are allergic to pramipexole or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Pramipexole Mylan.

Tell your doctor if you have (or have had) or develop any medical conditions or symptoms, especially any of the following:

- Kidney disease
- Hallucinations (seeing, hearing or feeling things that are not there). Most hallucinations are visual.
- Dyskinesia (e.g. abnormal, uncontrolled movements of the limbs). If you have advanced Parkinson's disease and are also taking levodopa, you might develop dyskinesia during the up titration of Pramipexole Mylan.
- Sleepiness and episodes of suddenly falling asleep
- Behavioural changes (e. g. pathological gambling, compulsive shopping), increased libido (e.g. increased sexual desire), binge eating.
- Psychosis (e.g. comparable with symptoms of schizophrenia)
- Vision impairment. You should have regular eye examinations during treatment with Pramipexole Mylan.

- Severe heart or blood vessels disease. You will need to have your blood pressure checked regularly, especially at the beginning of treatment. This is to avoid postural hypotension (a fall in blood pressure on standing up, which can make you dizzy or lose consciousness)

Tell your doctor if you or your family/carer notices that you are developing urges or cravings to behave in ways that are unusual for you and you cannot resist the impulse, drive or temptation to carry out certain activities that could harm yourself or others. These are called impulse control disorders and can include behaviours such as addictive gambling, excessive eating or spending, an abnormally high sex drive or preoccupation with an increase in sexual thoughts or feelings. Your doctor may need to adjust or stop your dose.

Tell your doctor if you or your family/carer notices that you are developing mania (agitation, feeling elated or over-excited) or delirium (decreased awareness, confusion, loss of reality). Your doctor may need to adjust or stop your dose.

Children and adolescents

Pramipexole Mylan is not recommended for use in children or adolescents under 18 years.

Other medicines and Pramipexole Mylan

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 Pramipexole Mylan together with antipsychotic medicines (medicines used to treat certain mental and emotional conditions. It helps to correct chemical imbalances in the brain which cause mental illnesses).

Take care if you are taking the following medicines:

- cimetidine (to treat excess stomach acid and stomach ulcers)
- amantadine (which can be used to treat Parkinson's disease)
- mexiletine (to treat irregular heartbeats, a condition known as ventricular arrhythmia)
- zidovudine (which can be used to treat HIV infection)
- cisplatin (to treat various types of cancers)
- quinine (which can be used for the prevention of painful night-time leg cramps and for the treatment of a type of malaria known as falciparum malaria (malignant malaria))
- procainamide (to treat irregular heart beat)

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

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 Pramipexole Mylan may affect your ability to drive and operate machinery.

Pramipexole Mylan with food, drink and alcohol

You should be cautious while drinking alcohol during treatment with Pramipexole Mylan as alcohol can increase the risk of sleepiness and suddenly falling asleep.

Pramipexole Mylan can be taken with or without food.

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Your doctor will then discuss with you if you should continue to take Pramipexole Mylan.

The effect of Pramipexole Mylan on the unborn child is not known. Therefore, do not take Pramipexole Mylan if you are pregnant unless your doctor tells you to do so.

Pramipexole Mylan should not be used during breast-feeding. Pramipexole Mylan can reduce the production of breast milk. Also, it can pass into the breast milk and can reach your baby. If use of Pramipexole Mylan is unavoidable, breast-feeding should be stopped.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Pramipexole Mylan can cause hallucinations (seeing, hearing or feeling things that are not there). If affected, do not drive or use machines.

Pramipexole Mylan has been associated with sleepiness and episodes of suddenly falling asleep, particularly when taken with alcohol or other medicines with a sedative effect. If you experience these side effects, you must not drive or operate machinery. You should tell your doctor if this occurs.

3. How to take Pramipexole Mylan

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The doctor will advise you on the right dosing.

You can take Pramipexole Mylan with or without food. Swallow the tablets with water.

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

During the first week, the recommended dose is one tablet Pramipexole Mylan 0.088 mg three times a day (equivalent to 0.264 mg daily):

	First Week
Number of tablets	One tablet Pramipexole Mylan 0.088 mg three times a day
Total daily dose (mg of base)	0.264

This will be increased every 5 - 7 days as directed by your doctor until your symptoms are controlled (maintenance dose).

	Second Week	Third Week
Number of tablets	One tablet Pramipexole Mylan 0.18 mg three times a day OR Two tablets Pramipexole Mylan 0.088 mg three times a day	One tablet Pramipexole Mylan 0.35 mg three times a day OR Two tablets Pramipexole Mylan 0.18 mg three times a day
Total daily dose (mg of base)	0.54	1.1

The recommended maintenance dose is 1.1 mg per day. However, your dose may have to be increased even further. If necessary, your doctor may increase your tablet dose up to a maximum of 3.3 mg of pramipexole a day. A lower maintenance dose of three Pramipexole Mylan 0.088 mg tablets a day is also possible.

	Lowest maintenance dose	Highest maintenance dose
Number of tablets	One tablet Pramipexole Mylan 0.088mg three times a day	One tablet Pramipexole Mylan 1.1mg three times a day
Total daily dose (mg of base)	0.264	3.3

Patients with kidney disease

If you have moderate or severe kidney disease, your doctor will prescribe a lower dose. In this case, you will have to take the tablets only once or twice a day. If you have moderate kidney disease, the

recommended starting dose is one tablet Pramipexole Mylan 0.088 mg twice a day up to a maximum of 1.57 mg a day.

In severe kidney disease, the recommended starting dose is just one tablet Pramipexole Mylan 0.088 mg once a day up to a maximum of 1.1 mg a day.

If you take more Pramipexole Mylan than you should

If you accidentally take too many tablets,

- contact your doctor or nearest hospital casualty department immediately for advice.
- you may experience vomiting, restlessness, or any of the side effects as described in section 4 'Possible side effects'.

If you forget to take Pramipexole Mylan

Do not worry. Simply leave out that dose completely and then take your next dose at the right time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Pramipexole Mylan

Do not stop taking Pramipexole Mylan without first talking to your doctor. If you have to stop taking this medicine, your doctor will reduce the dose gradually. This reduces the risk of worsening symptoms.

You should not stop treatment with Pramipexole Mylan abruptly. A sudden stop could cause you to develop a medical condition called neuroleptic malignant syndrome which may represent a major health risk. The symptoms include:

- akinesia (loss of muscle movement)
- rigid muscles
- fever
- unstable blood pressure
- tachycardia (increased heart rate)
- confusion
- depressed level of consciousness (e.g. coma)

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

If you notice any of the following side effects, seek urgent medical advice immediately by contacting your doctor or going to the nearest hospital casualty department straight away:

- Pneumonia (infection of the lungs that can cause fever, shivering, sweating, difficulty breathing, chest pain and feeling generally unwell)
- Heart failure (heart problems which can cause shortness of breath or a persistent cough, extreme tiredness or ankle swelling)*
- Signs of severe allergic reaction which can cause a rash or skin reaction, swelling of the face, tongue, lips or throat causing difficulty swallowing or breathing, sudden wheezing
- Inappropriate antidiuretic hormone secretion*, a hormone that causes the body to retain water and dilute the blood, reducing the amount of sodium. You may feel weak and confused with aching of muscles.

You may also experience the following side effects:

- Inability to resist the impulse, drive or temptation to perform an action that could be harmful to you or others, which may include:
 - Strong impulse to gambling excessively despite serious personal or family consequences.
 - Altered or increased sexual interest behaviour of significant concern to you or to others, for example, an increased sexual drive.
 - Uncontrolled excessive shopping or spending

- Binge eating (eating large amounts of food in a short time period) or compulsive eating (eating more food than normal and more than is needed to satisfy your hunger)
- Decreased awareness, confusion, loss of reality (delirium)
- Feeling agitated, elated or over-excited (mania)

Tell your doctor if you experience any of these behaviours; they will discuss ways of managing or reducing the symptoms.

Other possible side effects

If you suffer from Parkinson's disease, you may experience the following side effects:

Very common: may affect more than 1 in 10 people

- Abnormal, uncontrolled movements of the limbs (dyskinesia)
- Sleepiness
- Dizziness
- Nausea (feeling sick)

Common: may affect up to 1 in 10 people

- Seeing, hearing or feeling things that are not there (hallucinations)
- Confusion
- Tiredness (fatigue)
- Sleeplessness (insomnia)
- Excess of fluid, usually in the legs (peripheral oedema)
- Headache
- Low blood pressure (hypotension)
- Abnormal dreams
- Constipation
- Problems with your vision such as blurred or double vision or a reduced sharpness of vision
- Vomiting (being sick)
- Weight loss including decreased appetite

Uncommon: may affect up to 1 in 100 people

- Excessive fear for one's own well-being (paranoia)
- Delusion
- Excessive daytime sleepiness and suddenly falling asleep
- Memory disturbance (amnesia)
- Increased movements and inability to keep still (hyperkinesia)
- Weight increase
- Sexual desire problems (e.g. increased or decreased libido)
- Rash, itching
- Fainting
- Restlessness
- Shortness of breath (dyspnoea)
- Hiccups

For the side effects marked with * a precise frequency estimation is not possible, since these side effects were not observed in clinical studies among 2,762 patients treated with pramipexole. The frequency category is probably not greater than "uncommon".

In another indication, the same side effects as above have been reported with pramipexole but with different frequencies.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie;

e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Pramipexole Mylan

Keep this medicine out of the sight and reach of children.

Do not take this medicine after the expiry date which is stated on the carton, bottle or blister after EXP. The expiry date refers to the last day of that month.

Blister: Do not store above 25°C. Store in the original package in order to protect from light.

Bottle: Keep the bottle tightly closed in order to protect from light.

Do not throw away any medicines of via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Pramipexole Mylan contains

The active substance is pramipexole.

Each Pramipexole Mylan 0.088 mg tablet contains 0.088 mg of pramipexole base (as 0.125 mg of pramipexole dihydrochloride monohydrate).

Each Pramipexole Mylan 0.18 mg tablet contains 0.18 mg of pramipexole base (as 0.25 mg of pramipexole dihydrochloride monohydrate).

Each Pramipexole Mylan 0.7 mg tablet contains 0.7 mg of pramipexole base (as 1.0 mg of pramipexole dihydrochloride monohydrate).

The other ingredients are: mannitol, maize starch pregelatinised, sodium citrate anhydrous, silica colloidal anhydrous, magnesium stearate, hydroxypropylcellulose, crospovidone Type A.

What Pramipexole Mylan looks like and contents of the pack

Pramipexole Mylan 0.088 mg tablets are white to off white round, flat tablets marked with 'PX1' on one side of the tablet and 'M' on the other side.

Pramipexole Mylan 0.18 mg tablets are white to off white oval tablets marked with 'PX2' on one side of the tablet and 'M' on one side of the breakline on the other side.

Pramipexole Mylan 0.7 mg tablets are white to off white round, flat tablets marked with 'M' over 'PX4' on one side of the tablet and a breakline on the other side.

Pramipexole Mylan is available in blisters of 10, 20, 30, 60, 80, 90, 100 or 200 tablets.

Pramipexole Mylan is available in bottles of 30, 90, 100, 200 or 500 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

McDermott Laboratories Ltd. T/A Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Manufacturers

McDermott Laboratories Ltd. T/A Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Generics [UK] Ltd., Station Close, Potters Bar, Hertfordshire EN6 1TL, United Kingdom.

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria: Pramipexol Mylan 0.088 mg, 0.18 mg, 0.35 mg, 0.7 mg & 1.1 mg tabletten

Belgium: Pramipexole Mylan 0.088 mg, 0.18 mg, 0.35 mg, 0.7 mg & 1.1 mg tabletten

Cyprus: Pramipexole Mylan 0.088 mg, 0.18 mg, 0.35 mg, 0.7 mg & 1.1 mg tabletten

Czech Republic: Pramipexole Mylan 0.18 mg & 0.7 mg tablety
Denmark: Pramipexol Mylan 0.088 mg, 0.18 mg, 0.35 mg & 0.7 mg tabletter
France: Pramipexole Mylan 0.18 mg & 0.7 mg comprimé
Greece: Pramipexole Mylan 0.18 mg & 0.7 mg tabletten
Ireland: Pramipexole Mylan 0.088 mg, 0.18 mg & 0.7 mg tablets
Italy: Pramipexole Mylan 0.088 mg, 0.18 mg & 0.7 mg compresse
Romania: Pramipexol Mylan 0,088 mg comprimate, Pramipexol Mylan 0,18 mg comprimate,
Pramipexol Mylan 0,35 mg comprimate, Pramipexol Mylan 0,7 mg comprimate, Pramipexol Mylan
1,1 mg comprimate
The Netherlands: Pramipexol Mylan 0.088 mg, 0.18 mg, 0.35 mg, 0.7 mg tabletten
United Kingdom: Pramipexole Mylan 0.088 mg, 0.18 mg, 0.35 mg & 0.7 mg tablets

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