PACKAGE LEAFLET

Package leaflet: Information for the patient

Pramipexole 0.088 mg tablets
Pramipexole 0.18 mg tablets
Pramipexole 0.35 mg tablets
Pramipexole 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 is and what it is used for
2. What you need to know before you take Pramipexole
3. How to take Pramipexole
4. Possible side effects
5. How to store Pramipexole
6. Contents of the pack and other information

1. What Pramipexole is and what it is used for

Pramipexole 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 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).
- treat the symptoms of moderate to severe primary Restless Legs Syndrome in adults.

2. What you need to know before you take Pramipexole

Do not take Pramipexole

- 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.

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.
- Dystonia (inability of keeping your body and neck straight and upright (axial dystonia)). In particular, you may experience forward flexion of the head and neck (also called antecollis),

forward bending of the lower back (also called camptocormia) or sidewards bending of the back (also called pleurothotonus or Pisa Syndrome). If this happens, your doctor may want to change your medication.

- Sleepiness and episodes of suddenly falling asleep
- Psychosis (e.g. comparable with symptoms of schizophrenia)
- Vision impairment. You should have regular eye examination during treatment with Pramipexole.
- 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)
- Restless legs augmentation syndrome. If you experience that symptoms start earlier than usual in the evening (or even the afternoon), are more intense or involve larger parts of the affected limbs or involve other limbs. Your doctor may lower your dose or stop the treatment.

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 behaviors 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.

Tell your doctor if you experience symptoms such as depression, apathy, anxiety, fatigue, sweating or pain after stopping or reducing your Pramipexole treatment. If the problems persist more than a few weeks, your doctor may need to adjust your treatment.

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

Other medicines and Pramipexole
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 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 heartbeat)

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

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 may affect your ability to drive and operate machinery.

Pramipexole with food, drink and alcohol
You should be cautious while drinking alcohol during treatment with Pramipexole as alcohol can increase the risk of sleepiness and suddenly falling asleep.
Pramipexole 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 of pharmacist for advice before taking this medicine.
Your doctor will then discuss with you if you should continue to take Pramipexole.
The effect of Pramipexole on the unborn child is not known. Therefore, **do not** take Pramipexole if you are pregnant unless your doctor tells you to do so.

Pramipexole should not be used during breast-feeding. Pramipexole can reduce the production of breast milk. Also, it can pass into the breast milk and can reach your baby. If use of Pramipexole is unavoidable, breast-feeding should be stopped.
Ask your doctor or pharmacist for advice before taking any medicine.

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

Pramipexole contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Pramipexole

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 with or without food. Swallow the tablets with water.

Parkinson's disease
The recommended daily dose is to be taken divided into 3 equal doses.
During the first week, the recommended dose is one tablet Pramipexole 0.088 mg three times a day (equivalent to 0.264 mg daily):

	First Week
Number of tablets	One tablet Pramipexole 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 0.18 mg three times a day **OR** Two tablets Pramipexole 0.088 mg three times a day	One tablet Pramipexole 0.35 mg three times a day **OR** Two tablets Pramipexole 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 0.088 mg tablets a day is also possible.

	Lowest maintenance dose	**Highest maintenance dose**
Number of tablets	One tablet Pramipexole 0.088 mg three times a day	One tablet Pramipexole 1.1 mg 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 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 0.088 mg once a day up to a maximum of 1.1 mg a day.

Restless Legs Syndrome
The dose is usually taken once a day, in the evening, 2-3 hours before bedtime.
During the first week, the usual dose is 1 tablet Pramipexole 0.088 mg once a day (equivalent to 0.088 mg daily):

	1st week
Number of tablets	1 tablet Pramipexole 0.088 mg
Total daily dose (mg)	0.088

This will be increased every 4-7 days as directed by your doctor until your symptoms are controlled (maintenance dose).

	2nd week	3rd week	4th week
Number of tablets	1 tablet Pramipexole 0.18 mg OR 2 tablets Pramipexole 0.088 mg	1 tablet Pramipexole 0.35 mg OR 2 tablets Pramipexole 0.18 mg OR 4 tablets Pramipexole 0.088 mg	1 tablet Pramipexole 0.35 mg and 1 tablet Pramipexole 0.18 mg OR 3 tablets Pramipexole 0.18 mg OR 6 tablets Pramipexole 0.088 mg
Total daily dose (mg)	0.18	0.35	0.54

The daily dose should not exceed 6 tablets Pramipexole 0.088 mg or a dose of 0.54 mg (0.75 mg pramipexole salt).

If you stop taking your tablets for more than a few days and want to restart the treatment, you must start again at the lowest dose. You can then build up the dose again, as you did the first time. Ask your doctor for advice.

Your doctor will review your treatment after 3 months to decide whether or not to continue the treatment.

Patients with kidney disease
If you have severe kidney disease, Pramipexole may not be a suitable treatment for you.

If you take more Pramipexole 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

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
Do not stop taking Pramipexole 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.

If you suffer from Parkinson's disease you should not stop treatment with Pramipexole 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 stop or reduce Pramipexole you may also develop a medical condition called dopamine agonist withdrawal syndrome. The symptoms include depression, apathy, anxiety, fatigue, sweating or pain. If you experience these symptoms you should contact your physician.

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[+].

- Uncontrollable 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

Not known: frequency cannot be estimated from the available data
- After stopping or reducing your Pramipexole treatment: Depression, apathy, anxiety, fatigue, sweating or pain may occur (called dopamine agonist withdrawal syndrome or DAWS).

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".

If you suffer from Restless Legs Syndrome, you may experience the following side effects:

Very common: may affect more than 1 in 10 people
- Nausea (sickness)
- Symptoms that start earlier than usual, are more intense or involve other limbs (Restless legs augmentation syndrome).

Common: may affect up to 1 in 10 people
- Changes in sleep pattern, such as sleeplessness (insomnia) and sleepiness
- Tiredness (fatigue)
- Headache
- Abnormal dreams
- Constipation
- Dizziness
- Vomiting (being sick)

Uncommon: may affect up to 1 in 100 people
- Abnormal, uncontrolled movements of the limbs (dyskinesia)
- Increased movements and inability to keep still (hyperkinesia) +
- Excessive fear for one's own well-being (paranoia)+
- Delusion+
- Memory disturbance (amnesia)+
- Seeing, hearing or feeling things that are not there (hallucinations)
- Confusion
- Excessive daytime sleepiness and suddenly falling asleep
- Weight increase
- Low blood pressure (hypotension)
- Excess of fluid, usually in the legs (peripheral oedema)
- Fainting
- Restlessness
-Visual impairment
- Weight loss including decreased appetite
- Shortness of breath (dyspnoea)
- Hiccups

Not known: frequency cannot be estimated from the available data
- After stopping or reducing your Pramipexole treatment: Depression, apathy, anxiety, fatigue, sweating or pain may occur (called dopamine agonist withdrawal syndrome or DAWS).

For the side effects marked with + a precise frequency estimation is not possible, since these side effects were not observed in clinical studies among 1,395 patients treated with pramipexole. The frequency category is probably not greater than "uncommon".

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Pramipexole

Keep this medicine out of the sight and reach of children.
Do not use 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.

Do not store above 25ºC.
Blister: 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 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 contains
The active substance is pramipexole.

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

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

Each Pramipexole 0.35 mg tablet contains 0.35 mg of pramipexole base (as 0.5 mg of pramipexole dihydrochloride monohydrate).

Each Pramipexole 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.

What Pramipexole looks like and contents of the pack

Pramipexole 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 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 0.35 mg tablets are white to off white oval tablets marked with ‘PX3’ on one side of the tablet and ‘M’ on one side of the breakline on the other side.

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

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

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mylan, Potters Bar, Hertfordshire EN6 1TL, United Kingdom

Manufacturers

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