Package leaflet: Information for the user

Pramipexole Aurobindo 0.088 mg tablets
Pramipexole Aurobindo 0.18 mg tablets
Pramipexole Aurobindo 0.7 mg tablets
Pramipexole Aurobindo 1.1 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 Aurobindo is and what it is used for

Pramipexole Aurobindo contains the active substance pramipexole and 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 Aurobindo is used to:
- treat the symptoms of primary Parkinson's disease. It can be used alone or in combination with levodopa (another medicine for Parkinson's disease).

Pramipexole Aurobindo may also be authorised to treat other conditions which are not mentioned in this leaflet. Ask your doctor or pharmacist if you have further questions.

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

Do not take Pramipexole Aurobindo:
- if you are allergic to pramipexole or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Tell your doctor if you 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 uptitration of Pramipexole Aurobindo.
- Sleepiness and episodes of suddenly falling asleep

- Psychosis, (e.g. comparable with symptoms of schizophrenia)
- Vision impairment You should have regular eye examinations during treatment with Pramipexole Aurobindo.
- 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)
- Augmentation

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.

You may experience that symptoms start earlier than usual, be more intense and involve other limbs.

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

Other medicines and Pramipexole Aurobindo
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
You should avoid taking Pramipexole Aurobindo together with antipsychotic medicines.

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 the acquired immune deficiency syndrome (AIDS), a disease of the human immune system);
- 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 Aurobindo.

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 Aurobindo may affect your ability to drive and operate machinery.

Pramipexole Aurobindo with food and drink and alcohol
You should be cautious while drinking alcohol during treatment with Pramipexole Aurobindo.
Pramipexole Aurobindo can be taken with or without food.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, 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 Aurobindo.

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

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

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

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

Pramipexole Aurobindo 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.

3. How to take Pramipexole Aurobindo

Always take this medicine exactly as your doctor has told you. The doctor will advice you on the right dosing.
You can take Pramipexole Aurobindo with or without food. Swallow the tablets with water.

Parkinson's disease
The daily dose is to be taken divided into 3 equal doses.

During the first week, the usual dose is 1 tablet Pramipexole Aurobindo 0.088 mg three times a day (equivalent to 0.264 mg daily):

	1st week
Number of tablets	1 tablet Pramipexole Aurobindo 0.088 mg three times a day
Total daily dose (mg)	0.264

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

	2nd week	**3rd week**
Number of tablets	1 tablet Pramipexole Aurobindo 0.18 mg three times a day **or** 2 tablets Pramipexole Aurobindo 0.088 mg three times a day	1 tablet Pramipexole Aurobindo 0.35 mg three times a day **or** 2 tablets Pramipexole Aurobindo 0.18 mg three times a day
Total daily dose (mg)	0.54	1.1

The usual 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 Aurobindo 0.088 mg tablets a day is also possible.

	Lowest maintenance dose	**Highest maintenance dose**
Number of tablets	1 tablet Pramipexole Aurobindo 0.088 mg three times a day	1 tablet Pramipexole Aurobindo 1.1 mg three times a day
Total daily dose (mg)	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 usual starting dose is 1 tablet Pramipexole Aurobindo 0.088 mg twice a day. In severe kidney disease, the usual starting dose is just 1 tablet Pramipexole Aurobindo 0.088 mg a day.

If you take more Pramipexole Aurobindo 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 chapter 4 "Possible side effects".

If you forget to take Pramipexole Aurobindo
Do not worry. Simply leave out that dose completely and then take your next dose at the right time. Do not try to make up for the missed dose.

If you stop taking Pramipexole Aurobindo
Do not stop taking Pramipexole Aurobindo 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 Aurobindo 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.

Evaluation of these side effects is based on the following frequencies:

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

Very common: (may affect more than 1 in 10 people)
- Dyskinesia (e.g. abnormal, uncontrolled movements of the limbs)
- Sleepiness
- Dizziness
- Nausea (sickness)

Common: (may affect up to 1 in 10 people)
- Urge to behave in an unusual way
- Hallucinations (seeing, hearing or feeling things that are not there)
- Confusion
- Tiredness (fatigue)

- Sleeplessness (insomnia)
- Excess of fluid, usually in the legs (peripheral oedema)
- Headache
- Hypotension (low blood pressure)
- Abnormal dreams
- Constipation
- Visual impairment
- Vomiting (being sick)
- Weight loss including decreased appetite

Uncommon: (may affect up to 1 in 100 people)
- Paranoia (e.g. excessive fear for one's own well-being)
- Delusion
- Excessive daytime sleepiness and suddenly falling asleep
- Amnesia (memory disturbance)
- Hyperkinesia (increased movements and inability to keep still)
- Weight increase
- Allergic reactions (e.g.rash, itching, hypersensitivity)
- Fainting
- Cardiac failure (heart problems which can cause shortness of breath or ankle swelling)*
- Inappropriate antidiuretic hormone secretion*
- Restlessness
- Dyspnoea (difficulties to breathe)
- Hiccups
- Pneumonia (infection of the lungs)
- 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 gamble excessively despite serious personal or family consequences.
  - Altered or increased sexual interest and 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)*
- Delirium (decreased awareness, confusion, loss of reality)

Rare: (may affect up to 1 in 1,000 people)
- Mania (agitation, feeling elated or over-excited)

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

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 other indication treated with Pramipexole, you may experience the following side effects:

Very common: (may affect more than 1 in 10 people)

- Nausea (sickness)

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)
- Urge to behave in an unusual way*
- Cardiac failure (heart problems which can cause shortness of breath or ankle swelling)*
- Inappropriate antidiuretic hormone secretion*
- Dyskinesia (e.g. abnormal, uncontrolled movements of the limbs)
- Hyperkinesia (increased movements and inability to keep still)*
- Paranoia (e.g. excessive fear for one's own well-being)*
- Delusion*
- Amnesia (memory disturbance)*
- Hallucinations (seeing, hearing or feeling things that are not there)
- Confusion
- Excessive daytime sleepiness and suddenly falling asleep
- Weight increase
- Hypotension (low blood pressure)
- Excess of fluid, usually in the legs (peripheral oedema)
- Allergic reactions (e.g. rash, itching, hypersensitivity)
- Fainting
- Restlessness
- Visual impairment
- Weight loss including decreased appetite
- Dyspnoea (difficulties to breathe)
- Hiccups
- Pneumonia (infection of the lungs)*
- 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 gamble excessively despite serious personal or family consequences.*
  - Altered or increased sexual interest and 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)*

- Mania (agitation, feeling elated or over-excited)*
- Delirium (decreased awareness, confusion, loss of reality)*

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

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

IMB Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.imb.ie
e-mail: imbpharmacovigilance@imb.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Pramipexole Aurobindo

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

This medicinal product does not require any special storage conditions

Do not use this medicine after the expiry date which is stated on the carton and blister foil after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicine 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 Aurobindo contains

- The active substance is pramipexole.
  Each tablet contains 0.125 mg of pramipexole dihydrochloride monohydrate equivalent to 0.088 mg pramipexole.
  Each tablet contains 0.25 mg of pramipexole dihydrochloride monohydrate equivalent to 0.18 mg pramipexole.
  Each tablet contains 1.0 mg of pramipexole dihydrochloride monohydrate equivalent to 0.7 mg pramipexole.
  Each tablet contains 1.5 mg of pramipexole dihydrochloride monohydrate equivalent to 1.1 mg pramipexole.

- The other ingredients are: Mannitol (E421), maize starch, povidone K30, povidone K90, silica, colloidal anhydrous, magnesium stearate.

What Pramipexole Aurobindo looks like and contents of the pack
Tablet

Pramipexole Aurobindo 0.088 mg Tablets:
White to off-white, round, flat, beveled edge, uncoated tablets, debossed with ‘Y’ on one side ‘41’ on other side.

Pramipexole Aurobindo 0.18 mg Tablets:
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.
The tablet can be divided into equal halves.

Pramipexole Aurobindo 0.7 mg Tablets:
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.
The tablet can be divided into equal halves.

Pramipexole Aurobindo 1.1 mg Tablets:

White to off-white, round, flat, beveled edge, uncoated tablets, debossed with ‘Y’ and ‘46’ separated by score line on one side and plain with score line on other side.
The tablet can be divided into equal halves.

Pramipexole Aurobindo tablets are available in Polyamide/Aluminium foil /PVC - Aluminium foil blister and HDPE bottle with polypropylene cap containing cotton.

Pack sizes
Blister pack: 10, 20, 30, 50, 60, 90, 100 & 200 tablets
HDPE bottle pack: 90, 100 & 1000 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Milpharm Limited
Ares, Odyssey Business Park
West End Road
South Ruislip HA4 6QD
United Kingdom

Manufacturer
APL Swift Services (Malta) Limited
HF26, Hal Far Industrial Estate, Hal Far
Birzebbugia, BBG 3000
Malta

or

Milpharm Limited
Ares, Odyssey Business Park
West End Road
South Ruislip HA4 6QD
United Kingdom

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