Package leaflet: Information for the user

Prapexin 0.26 mg Prolonged-release tablets
Prapexin 0.52 mg Prolonged-release tablets
Prapexin 1.05 mg Prolonged-release tablets
Prapexin 2.1 mg Prolonged-release tablets
Prapexin 3.15 mg Prolonged-release 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 or nurse.
- 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Prapexin is and what it is used for
2. What you need to know before you take Prapexin
3. How to take Prapexin
4. Possible side effects
5. How to store Prapexin
6. Contents of the pack and other information

1. What Prapexin is and what it is used for

Prapexin 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.

Prapexin 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 Prapexin

Do not take Prapexin
- 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 **before taking** Prapexin. 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 Prapexin.
- 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 examinations during treatment with Prapexin.

- 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).

Tell your doctor if you or your family/caregiver 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.

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

Prapexin prolonged-release tablets are specially designed tablets from which the active ingredient is gradually released, once the tablet has been ingested. Parts of tablets may occasionally be passed and seen in the stool (faeces) and may look like whole tablets. Inform your doctor if you find tablet pieces in your faeces.

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

Other medicines and Prapexin
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 Prapexin 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 heartbeat).

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

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 Prapexin may affect your ability to drive and operate machinery.

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

Pregnancy and breast-feeding and fertility
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 Prapexin.

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

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

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

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

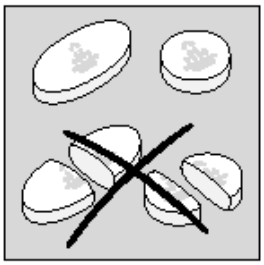
Prapexin has been associated with sleepiness and episodes of suddenly falling asleep, particularly in patients with Parkinson's disease. If you experience these side effects, you must not drive or operate machinery. You should tell your doctor if this occurs.

3. How to take Prapexin

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.

Take Prapexin Prolonged-release tablets only once a day and each day at about the same time.
You can take Prapexin with or without food. Swallow the tablets whole with water.

Do not chew, divide or crush the prolonged-release tablets.
If you do, there is a danger you could overdose, because
the medicine may be released into your body too quickly.



During the first week, the usual daily dose is 0.26 mg pramipexole. The dose will be increased every 5-7 days as directed by your doctor until your symptoms are controlled (maintenance dose).

Ascending dose schedule of Prapexin Prolonged-release tablets		
Week	Daily dose (mg)	Number of tablets
1	0.26	One Prapexin 0.26 mg Prolonged-release tablet.
2	0.52	One Prapexin 0.52 mg Prolonged-release tablet, OR two Prapexin 0.26 mg Prolonged-release tablets.
3	1.05	One Prapexin 1.05 mg Prolonged-release tablet, OR two Prapexin 0.52 mg Prolonged-release tablets, OR four Prapexin 0.26 mg Prolonged-release tablets.

The usual maintenance dose is 1.05 mg per day. However, your dose may have to be increased even further. If necessary, your doctor may increase your dose up to a maximum of 3.15 mg of pramipexole a day. A lower maintenance dose of one Prapexin 0.26 mg prolonged-release tablet a day is also possible.

Patients with kidney disease
If you have kidney disease, your doctor may advise you to take the usual starting dose of 0.26 mg prolonged-release tablets only every other day for the first week. After that, your doctor may increase the dosing frequency to one 0.26 mg prolonged-release tablet every day. If a further dose increase is necessary, your doctor may adjust it in steps of 0.26 mg pramipexole.

If you have serious kidney problems, your doctor may need to switch you to a different pramipexole medicine. If during treatment your kidney problems get worse, you should contact your doctor as soon as possible.

If you are switching from Pramipexole (immediate release) tablets
Your doctor will base your dose of Prapexin Prolonged-release tablets on the dose of Pramipexole (immediate release) tablets you were taking.

Take your Pramipexole (immediate release) tablets as normal the day before you switch. Then take your Prapexin Prolonged-release tablets next morning and do not take any more Pramipexole (immediate release) tablets.

If you take more Prapexin 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 Prapexin
If you forget to take a dose of Prapexin, but remember within 12 hours of your usual time, take your tablet straightaway and then take your next tablet at the usual time.

If you forget for more than 12 hours, simply take the next single dose at the usual time. Do not take a double dose to make up for a forgotten tablet dose.

If you stop taking Prapexin
Do not stop taking Prapexin 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 Prapexin 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 Prapexin 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 or nurse.

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:
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).

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

Tell your doctor if you experience any of these behaviours; 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”.

Reporting of side effects
If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance; website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Prapexin

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 after {EXP}.The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions.

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 Prapexin contains
- The active substance(s) is pramipexole.

Each tablet contains 0.26 mg, 0.52 mg, 1.05 mg, 2.1 mg, or 3.15 mg pramipexole as 0.375 mg, 0.75 mg, 1.5 mg, 3 mg, or 4.5 mg pramipexole dihydrochloride monohydrate, respectively.
- The other excipient(s) are hypromellose, calcium hydrogen phosphate, anhydrous, magnesium stearate, silica, colloidal anhydrous.

What Prapexin looks like and contents of the pack
Prapexin 0.26 mg Prolonged-release tablets: The tablets of 9 mm are white or nearly white, cylindrical, plans, with beveled edges and marked with 026 on one side
Prapexin 0.52 mg Prolonged-release tablets: The tablets of 10 mm are white or nearly white, cylindrical, biconvex and marked with 052 on one side
Prapexin 1.05 mg Prolonged-release tablets: The tablets of 10 mm are white or nearly white, cylindrical, biconvex, and marked with 105 on one side
Prapexin 2.1 mg Prolonged-release tablets: The tablets of 10 mm are white or nearly white, cylindrical, biconvex and marked with 210 on one side
Prapexin 3.15 mg Prolonged-release tablets: The tablets of 11 mm are white or nearly white, cylindrical, plans, with beveled edges and marked with 315 on one side

Blister OPA-Al-PVC/Al: 10, 30 and 100 prolonged-release tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers
Marketing Authorisation Holder
Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers
Ferrer Internacional, S.A., Joan Buscallà, 1-9, Sant Cugat del Vallès (Barcelona), 08173, Spain.
Laboratorios Normon, S.A., Ronda de Valdecarrizo, 6, Tres Cantos, 28760 Madrid, Spain.
Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, Sachsen-Anhalt, 39179 Barleben, Germany.

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

Austria:	Pramipexol Sandoz 0,26 mg - Retardtabletten Pramipexol Sandoz 0,52 mg - Retardtabletten Pramipexol Sandoz 1,05 mg - Retardtabletten Pramipexol Sandoz 2,1 mg - Retardtabletten Pramipexol Sandoz 3,15 mg- Retardtabletten
Belgium:	Pramipexol Retard Sandoz 0,26 mg tabletten met verlengde afgifte Pramipexol Retard Sandoz 0,52 mg tabletten met verlengde afgifte Pramipexol Retard Sandoz 1,05 mg tabletten met verlengde afgifte Pramipexol Retard Sandoz 2,1 mg tabletten met verlengde afgifte Pramipexol Retard Sandoz 3,15 mg tabletten met verlengde afgifte
Germany:	Pramipexol HEXAL® 0,26 mg Retardtabletten Pramipexol HEXAL® 0,52 mg Retardtabletten Pramipexol HEXAL® 1,05 mg Retardtabletten Pramipexol HEXAL® 2,1 mg Retardtabletten Pramipexol HEXAL® 3,15 mg Retardtabletten
Denmark:	Pramipexole "Sandoz"
France:	PRAMIPEXOLE SANDOZ LP 0,26 mg, comprimé à libération prolongée PRAMIPEXOLE SANDOZ LP 0,52 mg, comprimé à libération prolongée PRAMIPEXOLE SANDOZ LP 1,05 mg, comprimé à libération prolongée PRAMIPEXOLE SANDOZ LP 2,1 mg, comprimé à libération prolongée PRAMIPEXOLE SANDOZ LP 3,15 mg, comprimé à libération prolongée
Ireland:	Pramipexole Rowex 0.26 mg Prolonged-release tablets Pramipexole Rowex 0.52 mg Prolonged-release tablets Pramipexole Rowex 1.05 mg Prolonged-release tablets Pramipexole Rowex 2.1 mg Prolonged-release tablets Pramipexole Rowex 3.15 mg Prolonged-release tablets
Luxembourg:	Pramipexol Retard Sandoz 0,26 mg comprimés à libération prolongée Pramipexol Retard Sandoz 0,52 mg comprimés à libération prolongée Pramipexol Retard Sandoz 1,05 mg comprimés à libération prolongée Pramipexol Retard Sandoz 2,1 mg comprimés à libération prolongée Pramipexol Retard Sandoz 3,15 mg comprimés à libération prolongée
Netherlands:	Pramipexol Sandoz retard 0,26 mg, tabletten met verlengde afgifte Pramipexol Sandoz retard 0,52 mg, tabletten met verlengde afgifte Pramipexol Sandoz retard 1,05 mg, tabletten met verlengde afgifte Pramipexol Sandoz retard 2,1 mg, tabletten met verlengde afgifte Pramipexol Sandoz retard 3,15 mg, tabletten met verlengde afgifte
Sweden:	Pramipexole Sandoz, 0,26 mg depottablett Pramipexole Sandoz, 0,52 mg depottablett Pramipexole Sandoz, 1,05 mg depottablett Pramipexole Sandoz, 2,1 mg depottablett Pramipexole Sandoz, 3,15 mg depottablett

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