1.1.1 1.3.1.3 Patient Information Leaflet

Package leaflet: Information for the patient

Prapexin 0.088 mg Tablets
Prapexin 0.18 mg Tablets
Prapexin 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 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 to any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before taking Prapexin 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.

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

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 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
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 heart beat)

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 breastfeeding

Pregnancy

If you are pregnant or breastfeeding, 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.

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.

Breastfeeding

Prapexin should not be used during breastfeeding. 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, breastfeeding 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 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 Prapexin 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 Prapexin 0.088 mg three times a day (equivalent to 0.264 mg daily):

	1st week
Number of tablets	1 tablet Prapexin 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 Prapexin 0.18 mg three times a day OR 2 tablets Prapexin 0.088 mg three times a day	1 tablet Prapexin 0.35 mg three times a day **OR** 2 tablets Prapexin 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 Prapexin a day. A lower maintenance dose of three Prapexin 0.088 mg tablets a day is also possible.

	Lowest maintenance dose	**Highest maintenance dose**
Number of tablets	1 tablet Prapexin 0.088 mg three times a day	1 tablet Prapexin 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 Prapexin 0.088 mg twice a day. In severe kidney disease, the usual starting dose is just 1 tablet Prapexin 0.088 mg a day.

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 chapter 4 ("*Possible side effects"*).

If you forget to take Prapexin:
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 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. These 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 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 decrease 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:
- 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".

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. 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 Prapexin

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 tablet container, carton and blister after EXP. The expiry date refers to the last day of that month.

Alu-Alu blister
HDPE Bottle (for 0.18/ 0.7 mg)
Blister and HDPE bottle:
This medicinal product does not require any special storage conditions.
HDPE Bottle (for 0.088 mg)
Do not store above 25°C.

HDPE bottle:
After first opening: use within 3 months.
After first opening: do not store above 25°C

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 is pramipexole.

Prapexin 0.088 mg Tablets:
Each tablet contains 0.088 mg pramipexole (as 0.125 mg pramipexole dihydrochloride monohydrate).

Prapexin 0.18 mg Tablets:
Each tablet contains 0.18 mg pramipexole (as 0.25 mg pramipexole dihydrochloride monohydrate).

Prapexin 0.7 mg Tablets:
Each tablet contains 0.7 mg pramipexole (as 1.0 mg pramipexole dihydrochloride monohydrate).

The other ingredients are: mannitol, cellulose microcrystalline, maize starch, silica colloidal anhydrous, magnesium stearate.

What Prapexin looks like and contents of the pack
Prapexin 0.088 mg Tablets are white to off- white, uncoated, round shaped tablets, plain on both the sides.

Prapexin 0.18 mg Tablets are white to off- white, uncoated, oval shaped tablets with scoreline on both the sides.
The tablets can be divided into equal halves

Prapexin 0.7 mg Tablets are white to off- white, uncoated, round shaped tablets with scoreline on both the sides.
The tablets can be divided into equal halves

Oriented Poly Amide / Aluminium/ PVC// Aluminium blister: 30 and 100 tablets
closure (polypropylene), silica gel packet and polyester coil: 90 tablets

Not all pack sizes may be marketed.

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

Manufacturers
Salutas Pharma GmbH, Otto-von-Guericke Allee 1, 39179 Barleben, Germany.
Salutas Pharma GmbH, Dieselstrasse 5, 70839 Gerlingen, Germany.
Lek Pharmaceuticals d.d, Verovškova 57, 1526 Ljubljana, Slovenia.
Lek S.A., ul. Domaniewska 50 C, 02-672 Warszawa, Poland.
Lek Pharmaceuticals d.d., Trimlini 2D, 9220 Lendava, Slovenia.

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

Germany:	Prapexin 0,088 mg tabletten
	Prapexin 0,18 mg tabletten
	Prapexin 0,7 mg tabletten
Ireland:	Prapexin 0.088 mg Tablets
	Prapexin 0.18 mg Tablets
	Prapexin 0.7 mg Tablets

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