PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

GLEPARK 0.088mg tablets

GLEPARK 0.18mg tablets

GLEPARK 0.35mg tablets

GLEPARK 0.7mg tablets

(pramipexole)

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT GLEPARK IS AND WHAT IT IS USED FOR

GLEPARK 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.

GLEPARK 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).

2. BEFORE YOU TAKE GLEPARK

DO NOT take GLEPARK

- if you are allergic (hypersensitive) to pramipexole or to any of the other ingredients of the tablets (see Section 6, "Further information").

Take special care with GLEPARK

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 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 dyskinesias during the uptitration of GLEPARK.
- 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 GLEPARK
- 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).

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

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines, herbal remedies, health foods or supplements that you have obtained without a prescription.

You should avoid taking GLEPARK 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 GLEPARK.

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 GLEPARK may affect your ability to drive and operate machinery.

Taking GLEPARK with food and drink
You should be cautious while drinking alcohol during treatment with GLEPARK.
GLEPARK can be taken with or without food. Swallow the tablets with water.

Pregnancy and breast-feeding
Tell your doctor if you are pregnant, think you might be pregnant or if you intend to become pregnant. Your doctor will then discuss with you if you should continue to take GLEPARK .

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

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

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

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

GLEPARK 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 GLEPARK

Always take GLEPARK exactly as your doctor has told you. The doctor will advise you on the right dosing.

You can take GLEPARK 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 GLEPARK 0.088 mg tablet three times a day (equivalent to 0.264 mg daily):

	1st week
Number of tablets	1 tablet GLEPARK 0.088 mg tablet 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 GLEPARK 0.18 mg tablet three times a day **OR** 2 tablets GLEPARK 0.088 mg three times a day	1 tablet GLEPARK 0.35 mg tablet three times a day **OR** 2 tablets GLEPARK 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 GLEPARK 0.088 mg tablets a day is also possible.

	Lowest maintenance dose	**Highest maintenance dose**

Number of tablets	1 tablet GLEPARK 0.088 mg three times a day	1 tablet Pramipexole 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 GLEPARK 0.088 mg twice a day. In severe kidney disease, the usual starting dose is just 1 tablet GLEPARK 0.088 mg a day.

If you take more GLEPARK 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 GLEPARK

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 GLEPARK

Do not stop taking GLEPARK 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 GLEPARK 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 product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

You may 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 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 than normal and more than is needed to satisfy your hunger).

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

Like all medicines, GLEPARK can cause side effects, although not everybody gets them.
Evaluation of these side effects is based on the following frequencies:

Very common:	affects more than 1 user in 10
Common:	affects 1 to 10 users in 100
Uncommon:	affects 1 to 10 users in 1,000
Rare:	affects 1 to 10 users in 10,000
Very rare:	affects less than 1 user in 10,000

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

Very common:

- Dyskinesia (e.g. abnormal, uncontrolled movements of the limbs)
- Sleepiness
- Dizziness
- Nausea (sickness)

Common:

- Hallucinations (seeing, hearing or feeling things that are not there)
- Confusion
- Tiredness (fatigue)
- Excess of fluid, usually in the legs (peripheral oedema)
- Headache
- Abnormal dreams
- Constipation
- Sleeplessness (insomnia)
- Urge to behave in an unusual way
- Visual impairment
- Vomiting (being sick)
- Weight loss including decreased appetite
- Hypotension (low blood pressure)

Uncommon:

- 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
- Increased sexual desire (e.g. increased libido)
- Allergic reactions (e.g. rash, itching, hypersensitivity)
- Fainting
- Pathological gambling, especially when taking high doses of GLEPARK
- Hypersexuality
- Compulsive shopping
- Dyspnoea (difficulties to breathe)
- Pneumonia (infection of lungs)
- Cardiac failure (heart problems which can cause shortness of breath or ankle swelling)*
- Increased eating (binge eating, hyperphagia)*
- Restlessness
- 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".

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE GLEPARK

Keep out of the reach and sight of children.
Do not use GLEPARK after the expiry date which is stated on the carton and blister after <EXP>. The expiry date refers to the last day of that month.

Store in the original package to protect the tablets from light. This medicinal product does not require any special temperature storage conditions.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What GLEPARK contains

The active substance is pramipexole.

Each 0.088mg tablet contains 0.088mg of pramipexole base (as 0.125mg of pramipexole dihydrochloride monohydrate)
Each 0.18mg tablet contains 0.18mg of pramipexole base (as 0.25mg of pramipexole dihydrochloride monohydrate
Each 0.35 mg tablet contains 0.35mg of pramipexole base (as 0.5mg of pramipexole dihydrochloride monohydrate)
Each 0.7mg tablet contains 0.7mg of pramipexole base (as 1.0mg of pramipexole dihydrochloride monohydrate)

The other ingredients are:
mannitol (E 421); maize starch; povidone K 30 (E 1201); silica, colloidal anhydrous; magnesium stearate (E470b)

What GLEPARK looks like and contents of the pack
0.088mg tablets: circular, white, flat bevelled tablets engraved with 'PX" on one side and plain on the other side
0.18mg tablets: oval, white, flat bevelled uncoated tablets engraved with 'PX' and '1' on either side of score line on one side and score line on the other side. The tablet can be divided into equal halves.
0.35mg tablets: oval white, flat bevelled uncoated tablets engraved with 'PX' and '2' on either side of score line on one side and score line on other side. The tablet can be divided into equal halves.
0.7mg tablets: oval, white, flat bevelled uncoated tablets engraved with 'PX' and '3' on either side of score line on one side and score line on other side. The tablet can be divided into equal halves.

GLEPARK 0.088mg, 0.18mg, 0.35mg, 0.7mg tablets are available in aluminium/aluminium blisters of
30, 100 tablets

Not all pack sizes may be marketed

Marketing Authorisation Holder

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This medicinal product is authorised in the Member States of the EEA under the following names:
Bulgaria, Czech Republic , Denmark, Finland, France, Germany, Greece, Ireland, Lithuania
Romania, Slovak Republic, Spain, Sweden, The Netherlands, UK:
Glepark
Hungary: Pramipexole Glenmark tabletta

PA 1462/1/1-4

This leaflet was last revised in November 2012