

Glaxipria Film-Coated Tablet

Linagliptin (5mg)

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What Glaxipria is used for

Linagliptin is used for 'type 2 diabetes' in adults, if the disease cannot be adequately controlled with diet and exercise alone.

It is important to keep following the advice about diet and exercise that you have been given by your doctor or nurse.

How Glaxipria works

Glaxipria contains the active substance linagliptin which belongs to a group of medicines called "oral anti-diabetics". Oral anti-diabetics are used to treat high blood sugar levels. They work by helping the body reduce the level of sugar in your blood.

Before you use Glaxipria

- When you must not use it

If you are allergic to linagliptin or any of the other ingredients of this medicine.

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. It is unknown if Glaxipria is harmful to the unborn child.

Therefore, it is preferable to avoid using Glaxipria if you are pregnant. It is not known if Glaxipria passes into human breast milk. A decision must be made by your doctor whether to discontinue breast-feeding or to discontinue/abstain from Glaxipria therapy.

Children and adolescents

Glaxipria is not recommended for children and adolescents under 18 years. It is not effective in children and

adolescents between the ages of 10 and 17 years. It is not known if this medicine is safe and effective when used in children younger than 10 years.

- Before you start to take it

Talk to your doctor, pharmacist or nurse before taking Glaxipria if you:

- have type 1 diabetes (your body does not produce any insulin) or diabetic ketoacidosis (a complication of diabetes with high blood sugar, rapid weight loss, nausea or vomiting). Glaxipria should not be used to treat these conditions.
- have had allergic reactions to any other medicines that you take to control the amount of sugar in your blood.
- have or have had a disease of the pancreas.

If you have symptoms of acute pancreatitis, like persistent, severe stomach ache (abdominal pain), you should consult your doctor.

If you encounter blistering of the skin it may be a sign for a condition called bullous pemphigoid. Your doctor may ask you to stop Glaxipria.

Diabetic skin lesions are a common complication of diabetes. You are advised to follow the recommendations for skin and foot care that you are given by your doctor or nurse.

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular you should tell your doctor if you are using medicines containing any of the following active substances:

- Carbamazepine, phenobarbital or phenytoin. These may be used to control fits (seizures) or chronic pain.
- Rifampicin. This is an antibiotic used to treat infections such as tuberculosis.

How to use Glaxipria

- How much to use

The recommended dose of Glaxipria is one 5 mg tablet once a day.

- When to use it

You can take Glaxipria with or without food at any time of the day.

- How long to use it

Continue taking Glaxipria for as long as your doctor recommends.

- If you forget to use it

If you forget to take a dose of Glaxipria, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose.

Do not take a double dose to make up for a forgotten dose. Never take two doses on the same day.

- If you use too much (overdose)

If you take more Glaxipria than you should, talk to a doctor immediately.

While you are using it

- Things you must do

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Things you must not do

Do not stop taking Glaxipria without first consulting your doctor. Your blood sugar levels may increase when you stop taking Glaxipria. If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

- Things to be careful of

Driving and using machines

Glaxipria has no or negligible influence on the ability to drive and use machines.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some symptoms need immediate medical attention

You should stop taking Glaxipria and see your doctor immediately if you experience the following symptoms of low blood sugar: trembling, sweating, anxiety, blurred vision, tingling lips, paleness, mood change or confusion

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(hypoglycaemia).

Some patients have experienced allergic reactions (hypersensitivity; frequency uncommon, may affect up to 1 in 100 people) while taking Glaxipria alone or in combination with other medicinal products for the treatment of diabetes, which may be serious, including wheezing and shortness of breath (bronchial hyperreactivity; frequency not known, frequency cannot be estimated from the available data). Some patients experienced rash (frequency uncommon), hives (urticaria; frequency rare, may affect up to 1 in 1000 people), and swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing (angioedema; frequency rare). If you experience any of the signs of illness mentioned above, stop taking Glaxipria and call your doctor right away. Your doctor may prescribe medicine to treat your allergic reaction and a different medicine for your diabetes.

Some patients have experienced inflammation of the pancreas (pancreatitis; frequency uncommon, may affect up to 1 in 100 people) while taking Glaxipria alone for the treatment of diabetes.

STOP taking Glaxipria and contact a doctor immediately if you notice any of the following serious side effects:

- Severe and persistent pain in the abdomen (stomach area) which might reach through to your back, as well as nausea and vomiting, as it could be a sign of an inflamed pancreas (pancreatitis).

Some patients have had the following side effects while taking Glaxipria alone for the treatment of diabetes:

- Common: level of lipase in the blood increased.
- Uncommon: inflamed nose or throat (nasopharyngitis), cough, constipation (in combination with insulin), level of amylase in the blood increased
- Rare: painful sores, which occur in the mouth (mouth ulceration),

blistering of skin (bullous pemphigoid)

- Not known: level of triglyceride in the blood increased

Advise to consult doctor/pharmacist for further information.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring or visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Glaxipria

- Storage

Do not store above 30°C.

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 box and the blister. The expiry date refers to the last day of that month.

- Disposal

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.

Product Description

- What it looks like

Light pink, round, biconvex film-coated tablet debossed with '5' on one side.

- Ingredients

- Active ingredient:

Linagliptin

- Inactive ingredients

Excipients:

Mannitol

Crospovidone

Hypromellose

Silicon colloidal anhydrous

Magnesium stearate

MAL Number

MALxxxxxxxACZ

Manufacturer

PharOS MT Ltd.

HF62X, Hal Far Industrial Estate,
Birzebbugia BBG3000, Malta.

Product Registration Holder

Sandoz Products Malaysia Sdn. Bhd.
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