

GLYPVILO TABLETS

Vildagliptin (50mg)

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What Glypviso is used for

Each Glypviso tablet contains 50 mg of the active substance vildagliptin.

Glypviso is a medicine used to treat patients with type 2 diabetes whose condition cannot be controlled by diet and exercise alone. It helps to control the level of sugar in the blood. Such medicines are known as oral antidiabetics.

Type 2 diabetes develops if the body does not produce enough insulin or if the insulin that your body makes does not work as well as it should. It can also develop if the body produces too much glucagon.

Insulin is a substance that helps to lower the level of sugar in your blood, especially after meals. Glucagon is a substance that triggers the production of sugar by the liver, causing the blood sugar level to rise. The pancreas makes both of these substances.

How Glypviso works

Glypviso works by making the pancreas produce more insulin and less glucagon. Glypviso helps to control the blood sugar level.

Your doctor will prescribe Glypviso either alone or in combination with other antidiabetics depending on your condition.

It is important that you continue to follow the diet and/or exercise recommended to you while you are on treatment with Glypviso.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Before you use Glypviso

Follow all instructions given to you by your doctor or pharmacist carefully, even if they differ from the information contained in this leaflet.

- When you must not use it

- If you are allergic (hypersensitive) to vildagliptin or any of the other ingredients of Glypviso.

Pregnant women

Tell your doctor if you are pregnant, if you think you might be pregnant or if you are planning to become pregnant. Your doctor will discuss with you the potential risk of taking Glypviso during pregnancy.

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

Breast-feeding mothers

Do not breast-feed during treatment with Glypviso. Ask your doctor or pharmacist for advice before taking any medicine while you are breastfeeding.

- Before you start use it

Take special care with Glypviso

- If you are pregnant or plan to become pregnant.
- If you are breast-feeding.
- If you have kidney problems.
- if you have liver problems.
- if you are suffering from heart failure, your doctor will decide whether or not to prescribe Glypviso depending on the degree of your condition.
- Glypviso is not a substitute for insulin. You should therefore neither receive Glypviso for the treatment of type 1 diabetes (i.e. your body does not produce insulin at all) nor for the treatment of a condition called diabetic ketoacidosis.

If any of these apply to you, tell your doctor before you take Glypviso.

Monitoring your Glypviso treatment

Your doctor should ensure that the following tests are performed:

- Blood and urine tested for sugar regularly
- Check how your liver functions:
 - at start of treatment
 - every 3 months during the first year of treatment and regularly thereafter

- if your doctor has told you to stop treatment with Glypviso because of liver problems you should never start taking Glypviso again

Glypviso and older people

Glypviso can be used by elderly patients.

Glypviso in children/adolescents

There is no information available on the use of Glypviso in children and adolescents (age below 18 years). The use of Glypviso in these patients is therefore not recommended.

- Taking other medicines

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

Remember also those not prescribed by a doctor.

How to use Glypviso

Follow all instructions given to you by your doctor and pharmacist carefully, even if they differ from the ones given in this leaflet. Do not take more Glypviso than your doctor has prescribed.

- How much to use

Your doctor will tell you exactly how many tablets of Glypviso to take.

The usual dose using Glypviso 50mg tablets is 50 mg or 100 mg a day. The 50 mg dose should be taken as 50 mg once a day. The 100 mg dose should be taken as 50 mg twice a day. Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.

Your doctor will prescribe Glypviso either alone or in combination with other antidiabetics, depending on your condition.

- When to use it

Glypviso 50mg tablets should be taken in the morning (50mg once a day) or in the morning and evening (50mg twice daily).

Glypviso can be taken with or without a meal.

The tablets should be swallowed whole with a glass of water.

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- How long to use it

Continue taking Glypviso for as long as your doctor recommends.

You may have to stay on this treatment for a long period of time.

Your doctor will regularly monitor your condition to check that the treatment is having the desired effect.

If you doctor has told you to stop treatment with Glypviso because of liver problems you should never start taking Glypviso again.

If you have questions about how long to take Glypviso, talk to your doctor.

- If you forget to use it

If you forget to take Glypviso, take it as soon as you remember. Then take your next dose at the usual time. However, if it is almost time for your next dose, skip the dose you missed. Do not take a double dose to make up for the forgotten tablet.

- If you use too much (overdose)

If you have accidentally taken too many Glypviso tablets, or if someone else has taken your medicine, talk to your doctor straight away. You may require medical attention. Show the doctor the pack if possible.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using Glypviso.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Glypviso to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

Patients experiencing dizziness should avoid driving vehicles or using machines.

Side effects

Glypviso can have some side effects in some people. Some patients have experienced the following side effects while taking Glypviso or in combination with another antidiabetic medication:

Some symptoms need immediate medical attention

You should stop taking Glypviso and see your doctor immediately if you experience the following symptoms:

- Swollen face, tongue or throat, difficulty swallowing, difficulty breathing, sudden onset of rash or hives (symptoms of severe allergic reaction called 'angioedema').
- Yellow skin and/or eyes, nausea, loss of appetite, dark- colored urine (possible symptoms of liver problems).
- Severe upper stomach pain (possible symptom of inflamed pancreas).
- Headache, drowsiness, weakness, dizziness, confusion, irritability, hunger, fast heartbeat, sweating, feeling jittery (possible symptoms of low level of sugar in the blood known as 'hypoglycemia')

Other side effects

Common side effects (likely to occur in more than 1 in 10 patients)

Uncommon side effects (likely to occur in fewer than 1 in 100 patients).

Some patients have had the following side effects while taking Glypviso alone:

- Common: Dizziness.
- Uncommon: Headache, constipation, swollen hands, ankles or feet (edema).

Some patients have had the following side effects while taking Glypviso and metformin:

- Common: Trembling, headache, dizziness.

Some patients have had the following side effects while taking Glypviso and a sulphonylurea:

- Trembling, headache, dizziness, weakness

Some patients have had the following side effects while taking Glypviso and a glitazone:

- Common: Weight increase, swollen hands, ankles or feet (oedema)
- Uncommon: Headache

Some patients have had the following side effects while taking Glypviso and insulin (with or without metformin):

- Common: Headache, chills, nausea (feeling sick), decreased blood sugar, heartburn
- Uncommon: Diarrhoea, flatulence

Some patients have had the following side effects while taking Glypviso with metformin and a sulphonylurea:

- Common: Dizziness, trembling, weakness, excessive sweating

If any of these affects you severely, **tell your doctor.**

Some patients have experienced other side effects while taking Glypviso alone or in combination with another antidiabetic medication:

- Itchy rash, areas of peeling skin or blisters, joint pain

If any of these affects you severely, **tell your doctor.**

If you notice any other side effects not mentioned in this leaflet, please tell your doctor or pharmacist.

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

Storage and Disposal of Glypviso

- Storage

Keep out of the reach and sight of children.

Do not store above 30°C.

Store in the original package in order to protect from moisture.

Do not use your medicine after the expiry date which is stated on the box after 'EXP'. 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

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medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

White or almost white, round tablets with bevelled edges.

Supply

Blister pack: 56 tablets in a box.

- Ingredients

- Active ingredient

Each tablet contains 50 mg vildagliptin.

- Inactive ingredients

The other ingredients are mannitol, hydroxypropylcellulose (type EF), low-substituted hydroxypropylcellulose, microcrystalline cellulose (type 112), sodium starch glycolate (type A), colloidal anhydrous silica and sodium stearyl fumarate.

- MAL number:

MAL*****

Manufacturer

KRKA, d.d., Novo mesto,
Šmarješka cesta 6,
8501 Novo mesto,
Slovenia.

Product Registration Holder

Pahang Pharmacy Sdn. Bhd.
Lot 5979, Jalan Teratai,
5 ½ Mile off Jalan Meru, Klang,
Selangor, Malaysia.

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10/10/2024

Serial Number

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