NOVARTIS

Galvus 50 mg, tablet

Vildagliptin 50 mg per tablet

PATIENT INFORMATION LEAFLET

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GALVUS 50 mg

Vildagliptin 50 mg

Contains Sugar (Lactose)

Read all of this leaflet carefully before you start taking GALVUS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- Galvus has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this Leaflet

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

1. What GALVUS is and what it is used for

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

GALVUS 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.

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

Your doctor has prescribed GALVUS in combination with other antidiabetics depending on your condition.

It is important that you continue to follow the diet and/or exercise advised for you, whilst you are on treatment with GALVUS.

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

2. What you need to know before you take GALVUS

Follow all instructions given to you by your doctor or pharmacist carefully.

Do not take GALVUS:

- If you are allergic (hypersensitive) to vildagliptin or any of the other ingredients of GALVUS.
- If you have liver problems.

Warnings and special precautions

Take special care with GALVUS:

- If you are suffering from heart failure, your doctor will decide whether or not to prescribe GALVUS depending on the degree of your condition.
- GALVUS is not a substitute for insulin. You should therefore not receive GALVUS for the treatment of type I diabetes.
- If you experience joint pain, sometimes severe.
- If you experience rash or areas of peeling skin or blisters.

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

Your doctor should ensure the following:

- your blood and urine should be tested for sugar regularly
- your liver function should be checked:

  - at start of treatment
  - every 3 months during the first year of treatment and regularly thereafter.

If your doctor told you to stop your treatment with GALVUS because of liver problems, you should never start taking GALVUS again.

Children:

There is no information available on the use of GALVUS in children (less than 18 years). The use of GALVUS in these patients is therefore not recommended.

Other medicines and GALVUS:

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

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of GALVUS with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

GALVUS with food and drink:

GALVUS can be taken with or without a meal.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

The safety of GALVUS in pregnancy and breastfeeding has not been established.

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

Driving and using machines:

GALVUS may cause dizziness.

If you experience dizziness while taking GALVUS, you should avoid driving vehicles or using machines.

GALVUS contains lactose:

GALVUS contains an ingredient called lactose (milk sugar). If you have severe lactose intolerance eg, galactosaemia, galactose intolerance, or glucose-galactose malabsorption, tell your doctor before taking GALVUS.

HOW TO TAKE GALVUS

Follow all instructions given to you by your doctor and pharmacist carefully. Do not take more GALVUS than your doctor has prescribed. Do not share medicines prescribed for you with others.

How much GALVUS to take:

Your doctor has prescribed GALVUS in combination with other antidiabetics if one medicine alone is not sufficient to control your blood sugar level.

Do not share medicines prescribed for you with any other person.

Always take GALVUS exactly as your doctor has told you. Check with your doctor if you are not sure.

The usual dose of GALVUS is 50 mg once a day (taken in the morning) or 50 mg twice a day (one tablet in the morning and in the evening).

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

Continue taking GALVUS every day for as long as your doctor tells you. You may have to stay on the 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 your doctor has told you to stop your treatment with GALVUS because of liver problems you should never start taking GALVUS again.

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

If you take more GALVUS than you should:

If you have accidentally taken too many GALVUS tablets, or if someone else has used your medicine tell your doctor or pharmacist straight away. You may need medical attention. Show them the pack, if possible. If neither is available, go to the nearest hospital or poison centre.

If you forget to take GALVUS:

If you forget to take GALVUS, 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 forgotten individual doses.

4. POSSIBLE SIDE EFFECTS

GALVUS can have side effects. Not all side effects reported for GALVUS are included in this leaflet. Should your general health worsen while taking GALVUS, please consult your doctor, pharmacist or other healthcare professional for advice.

The following side effects may occur whilst taking GALVUS:

Some symptoms need immediate medical attention:
You should stop taking GALVUS and see your doctor immediately if you experience the following symptoms:

- Swollen face, tongue, lips or throat, difficulty swallowing, difficulty breathing, sudden onset of rash or hives (symptoms of severe allergic reaction called ‘angioedema’).
- Yellow skin and eyes, nausea, loss of appetite, light-coloured urine (possible symptoms of liver problems).

- Severe upper stomach pain (possible sign of inflamed pancreas).

Other side effects:

Frequent: Trembling, headache, dizziness, weakness, nausea, decreased blood glucose, heartburn, constipation, swollen legs, chills, low level of glucose (sugar) in the blood, excessive sweating.

Less frequent: Diarrhoea, flatulence, itchy rash, (localised) areas of peeling of skin or blisters, joint pains.

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of GALVUS.

5. How to store GALVUS

- Store at or below 30 °C in the original package. Protect from moisture.
- Do not remove blister from carton until required for use.
- Do not use after the expiry date shown on the box.
- Do not use any GALVUS pack that is damaged or shows signs of tampering.
- Keep all medicines out of the reach and sight of children.

6. Content of the pack and other information

What GALVUS contains:

What GALVUS looks like and contents of the pack

GALVUS is a white to light yellowish, round, flat, bevelled edged tablet. One side is debossed with "NVR", and the other side with "FB".

Galvus is packed in 28 or 56 tablets in PA/Al/PVC (polyamide / aluminium / polyvinylchloride) blisters with an aluminium foil backing.

Holder of certificate of registration:

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