

# GALVUS®

## Vildagliptin 50 mg Tablets

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### What Galvus 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.

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 Galvus works

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

Your doctor will prescribe Galvus 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 Galvus.

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

### Before you take Galvus

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 Galvus.

### 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 Galvus 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 Galvus.

Ask your doctor or pharmacist for advice before taking any medicine while you are breast-feeding.

#### Before you start to use it

#### **Take special care with Galvus**

- 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 Galvus depending on the degree of your condition.
- Galvus is not a substitute for insulin. You should therefore neither receive Galvus 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 Galvus.

### Monitoring your Galvus 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 Galvus because of liver problems you should never start taking Galvus again.

### Galvus and older people

Galvus can be used by elderly patients.

### Galvus in children/adolescents

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

### Important information about some of the ingredients of Galvus

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

#### 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 Galvus

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 Galvus than your doctor has prescribed.

### How much to use

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

The usual dose using Galvus 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 Galvus either alone or in combination with other antidiabetics, depending on your condition.

### When to use Galvus

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

Galvus can be taken with or without a meal.

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

### How long to use Galvus

Continue taking Galvus every day for as long as your doctor tells you. 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 your doctor has told you to stop 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 forget to use 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 the forgotten tablet.

### If you use too much (overdose)

If you have accidentally taken too many tablets, or if someone else has taken your medicine, talk to a doctor straight away. You may

require medical attention. Show the doctor the pack if possible.

### **While you are using Galvus**

#### 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 taking Galvus.

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 Galvus 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**

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

#### **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 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, weakness, drowsiness, 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 Galvus alone:

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

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

- Common: Trembling, headache, dizziness.

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

- Common: Trembling, headache, dizziness, weakness

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

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

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

- Common: Headache, chills, nausea, decreased blood sugar, heartburn.
- Uncommon: Diarrhea, flatulence.

Some patients have had the following side effects while taking Galvus 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 Galvus 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 [npa.gov.my](http://npa.gov.my) [Consumers→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

#### **Storage and disposal of Galvus**

##### **Storage**

- Do not store Galvus above 30°C.
- Do not use after the expiry date shown on the box.
- Store in the original package.
- Do not use any Galvus pack that is damaged or shows signs of tampering.
- Keep out of the reach and sight of children.

##### **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**

The tablet is white to light yellowish in color and round in shape. One side is debossed with "NVR", and the other side with "FB".

Each tablet contains 50 mg Vildagliptin.

##### **Ingredients:**

###### ***- Active Ingredients***

The active substance of Galvus is vildagliptin.

###### ***- Inactive Ingredients***

The other ingredients are lactose anhydrous, microcrystalline cellulose, sodium starch glycolate, magnesium stearate.

##### **MAL Number:**

Galvus 50mg tablet:  
MAL20081792ARZ

##### **Manufacturer**

Lek Pharmaceuticals d.d.,  
Verovskova ulica 57,  
Ljubljana 1526, Slovenia.

##### **Product Registration Holder**

Novartis Corporation (Malaysia)  
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