

Package leaflet: Information for the user

Galvus® 50 mg tablets vildagliptin

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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
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1. What Galvus is and what it is used for

The active substance of Galvus, vildagliptin, belongs to a group of medicines called “oral antidiabetics”.

Galvus is used to treat adult patients with type 2 diabetes. It is used when diabetes cannot be controlled by diet and exercise alone. It helps to control the level of sugar in the blood. Your doctor will prescribe Galvus either alone or together with certain other antidiabetic medicines which you will already be taking, if these have not proved sufficiently effective to control diabetes.

Type 2 diabetes develops if the body does not make enough insulin or if the insulin that the 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 which helps to lower the level of sugar in the blood, especially after meals. Glucagon is a substance which 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. This helps to control the blood sugar level. This medicine has been shown to reduce blood sugar, which may help to prevent complications from your diabetes. Even though you are now starting a medicine for your diabetes, it is important that you continue to follow the diet and/or exercise which has been recommended for you.

2. What you need to know before you take Galvus

Do not take Galvus:

- if you are allergic to vildagliptin or any of the other ingredients of this medicine (listed in section 6). If you think you may be allergic to vildagliptin or any of the other ingredients of Galvus, do not take this medicine and talk to your doctor.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Galvus

- if you have type 1 diabetes (i.e. your body does not produce insulin) or if you have a condition called diabetic ketoacidosis.
- if you are taking an anti-diabetic medicine known as a sulphonylurea (your doctor may want to reduce your dose of the sulphonylurea when you take it together with Galvus in order to avoid low blood glucose [hypoglycaemia]).
- if you have moderate or severe kidney disease (you will need to take a lower dose of Galvus).
- if you are on dialysis.
- if you have liver disease.
- if you suffer from heart failure.
- if you have or have had a disease of the pancreas.

If you have previously taken vildagliptin but had to stop taking it because of liver disease, you should not take this medicine.

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. You are also advised to pay particular attention to new onset of blisters or ulcers while taking Galvus. Should these occur, you should promptly consult your doctor.

A test to determine your liver function will be performed before the start of Galvus treatment, at three-month intervals for the first year and periodically thereafter. This is so that signs of increased liver enzymes can be detected as early as possible.

Children and adolescents

The use of Galvus in children and adolescents up to 18 years of age is not recommended.

Other medicines and Galvus

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

Your doctor may wish to alter your dose of Galvus if you are taking other medicines such as:

- thiazides or other diuretics (also called water tablets)
- corticosteroids (generally used to treat inflammation)
- thyroid medicines
- certain medicines affecting the nervous system.

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.

You should not use Galvus during pregnancy. It is not known if Galvus passes into breast milk. You should not use Galvus if you are breast-feeding or plan to breast-feed.

Driving and using machines

If you feel dizzy while taking Galvus, do not drive or use machines.

Galvus contains lactose

Galvus contains lactose (milk sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Galvus

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

How much to take and when

The amount of Galvus people have to take varies depending on their condition. Your doctor will tell you exactly how many tablets of Galvus to take. The maximum daily dose is 100 mg.

The usual dose of Galvus is either:

- 50 mg daily taken as one dose in the morning if you are taking Galvus with another medicine called a sulphonylurea.
- 100 mg daily taken as 50 mg in the morning and 50 mg in the evening if you are taking Galvus alone, with another medicine called metformin or a glitazone, with a combination of metformin and a sulphonylurea, or with insulin.
- 50 mg daily in the morning if you have moderate or severe kidney disease or if you are on dialysis.

How to take Galvus

- Swallow the tablets whole with some water.

How long to take Galvus

- Take Galvus every day for as long as your doctor tells you. You may have to take this treatment over a long period of time.
- Your doctor will regularly monitor your condition to check that the treatment is having the desired effect.

If you take more Galvus than you should

If you take too many Galvus tablets, or if someone else has taken your medicine, **talk to your doctor straight away**. Medical attention may be needed. If you need to see a doctor or go to the hospital, take the pack with you.

If you forget to take Galvus

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

If you stop taking Galvus

Do not stop taking Galvus unless your doctor tells you to. If you have questions about how long to take this medicine, talk to your doctor.

4. Possible 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 Galvus and see your doctor immediately if you experience the following side effects:

- Angioedema (rare: may affect up to 1 in 1,000 people): Symptoms include swollen face, tongue or throat, difficulty swallowing, difficulties breathing, sudden onset rash or hives, which may indicate a reaction called “angioedema”.

- Liver disease (hepatitis) (rare): Symptoms include yellow skin and eyes, nausea, loss of appetite or dark-coloured urine, which may indicate liver disease (hepatitis).
- Inflammation of the pancreas (pancreatitis) (frequency not known): Symptoms include severe and persistent pain in the abdomen (stomach area), which might reach through to your back, as well as nausea and vomiting.

Other side effects

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

- Common (may affect up to 1 in 10 people): Trembling, headache, dizziness, nausea, low blood glucose
- Uncommon (may affect up to 1 in 100 people): Tiredness

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

- Common: Trembling, headache, dizziness, weakness, low blood glucose
- Uncommon: Constipation
- Very rare (may affect up to 1 in 10,000 people): Sore throat, runny nose

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

- Common: Weight increase, swollen hands, ankle or feet (oedema)
- Uncommon: Headache, weakness, low blood glucose

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

- Common: Dizziness
- Uncommon: Headache, constipation, swollen hands, ankle or feet (oedema), joint pain, low blood glucose
- Very rare: Sore throat, runny nose, fever

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

- Common: Dizziness, tremor, weakness, low blood glucose, excessive sweating

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

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

Since this product has been marketed, the following side effects have also been reported:

- Frequency not known (cannot be estimated from the available data): Itchy rash, inflammation of the pancreas, localised peeling of skin or blisters, muscle pain

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Ireland	HPRA Pharmacovigilance Earlsfort Terrace IRL - Dublin 2 Tel: +353 1 6764971 Fax: +353 1 6762517 Website: www.hpra.ie e-mail: medsafety@hpra.ie
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Malta	ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal
United Kingdom	Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store Galvus

- 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 blister and the carton after “EXP”. The expiry date refers to the last day of that month.
- Store in the original package in order to protect from moisture.
- Do not use any Galvus pack that is damaged or shows signs of tampering.

6. Contents of the pack and other information

What Galvus contains

- The active substance is vildagliptin.
Each tablet contains 50 mg vildagliptin.
- The other ingredients are lactose anhydrous, microcrystalline cellulose, sodium starch glycolate (type A) and magnesium stearate.

What Galvus looks like and contents of the pack

Galvus 50 mg tablets are round, white to light yellowish and flat, with “NVR” on one side and “FB” on the other.

Galvus 50 mg tablets are available in packs containing 7, 14, 28, 30, 56, 60, 90, 112, 180 or 336 tablets and in multipacks comprising 3 cartons, each containing 112 tablets.

Not all pack sizes may be marketed in your country.

Marketing Authorisation Holder

Novartis Europharm Limited
Vista Building
Elm Park, Merrion Road
Dublin 4
Ireland

Manufacturer

Novartis Pharma GmbH
Roonstraße 25
D-90429 Nuremberg
Germany

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Ireland

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Malta

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Tel: +356 2122 2872

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency website:
<http://www.ema.europa.eu>