

Information for patients

Read this package leaflet carefully before taking this medicine.

This medicine has been prescribed for you personally. Do not pass it on to anyone else. It may harm them even if their symptoms are the same as yours. Keep this leaflet. You may want to read it again later.

Galvus®

What Galvus is and what it is used for

Galvus is a medicine used to treat type 2 diabetes (diabetes mellitus). It is prescribed when the illness cannot be treated through diet and exercise alone. It contains the active substance vildagliptin, which decreases blood sugar levels.

When you have type 2 diabetes, your body does not produce enough insulin and/or produces too much glucagon. The effect of your body's own insulin may also be reduced. Insulin is a substance (produced by the pancreas) that helps to decrease blood sugar levels, especially after meals. Glucagon is another substance that is produced by the pancreas. It stimulates sugar production, which increases blood sugar levels. Galvus makes the pancreas produce insulin and reduces glucagon production. This is how Galvus helps to control blood sugar levels.

To control your blood sugar level, your doctor can prescribe either treatment with Galvus alone or together with another oral antidiabetic medicine or insulin. This medicine is used on prescription from a doctor.

Additional information to be aware of

Proper blood sugar control does not depend solely on medical treatment. Following your diet and getting enough exercise are

also important. You should therefore follow the instructions of your doctor or diabetes advisor in this regard.

Do not take Galvus

Do not take Galvus if you are allergic to any of its ingredients.

Warnings and precautions

If you become dizzy, you should not drive or use machines. You should not take Galvus if you suffer from a liver function disorder, type 1 diabetes or ketoacidosis. If you have previously stopped Galvus treatment due to a liver function disorder, you should not take Galvus again.

If you take Galvus in combination with another oral antidiabetic medicine or insulin, the risk of developing a low blood sugar level (hypoglycaemia) may be increased. Your doctor will lower their dosage if necessary. Cases of pancreas inflammation (pancreatitis) have been reported in patients taking Galvus. Pancreatitis is a serious, potentially life-threatening illness. Stop

taking Galvus and consult your doctor if you experience severe, continuous abdominal pain with or without vomiting, as you may be suffering from pancreatitis. Consult your doctor immediately if you experience unexplained muscle pain, muscle sensitivity or muscle weakness. In rare cases muscle problems may be serious, including muscle breakdown, which can cause kidney damage. The risk may be higher at higher dosages of Galvus and in patients with abnormal kidney function. This medicine contains lactose. Please only take Galvus tablets after talking to your doctor if you have a known intolerance to certain sugars. People with the rare hereditary problems of galactose intolerance, lactase deficiency or glucose-galactose malabsorption should not take Galvus tablets. Galvus tablets contain less than 1 mmol (23 mg) of sodium per tablet, making them practically "sodium-free". Inform your doctor or pharmacist if you:

- suffer from any other illnesses,

- have any allergies or
- are taking any other medicines (including non-prescription medicines).

Pregnancy and breast-feeding

Inform your doctor if you are pregnant or become pregnant during treatment. You may only take Galvus during pregnancy with the express permission of your doctor.

Breast-feeding

It is not known whether vildagliptin, the active substance of Galvus, passes into breast milk. You should not take Galvus if you are breast-feeding.

How to take Galvus

Your doctor will tell you at which times of day you should take Galvus and how many Galvus tablets to take. When Galvus is the only medicine you take to treat your type 2 diabetes, the recommended Galvus dose is 1 tablet once or twice daily. If you also need to take a medicine containing the active

substance metformin, the recommended dose of Galvus is 1 tablet twice daily.

With all other medicines that reduce blood sugar levels, the recommended dose of Galvus is 1 tablet once to twice daily. The maximum daily dose of 1 tablet twice daily must not be exceeded.

The use and safety of Galvus in children and adolescents (children under 18 years of age) has not been tested; therefore, Galvus should not be taken by children and adolescents. The tablets should be swallowed with a glass of water. They may be taken with or without food. Take Galvus every day for as long as your doctor has prescribed. Treatment may be long-term. Regular check-ups with your doctor are important to ensure that the treatment is having the desired effect.

Only stop treatment with Galvus if instructed to do so by your doctor. If you forget to take a tablet, take it as soon as you remember and then take your next tablet on the next day at the usual time.

Do not change the prescribed dosage yourself. If you think the effect of your medicine is too weak or too strong, talk to your doctor or pharmacist.

Possible side effects

The following side effects may occur when taking Galvus:

Common (affecting 1 to 10 in 100 users)

Dizziness, trembling, nausea, chills, heartburn, headache, low blood sugar (hypoglycaemia), weakness, severe sweating.

Uncommon (affecting 1 to 10 in 1,000 users)

Swollen hands, ankles and feet* (peripheral oedema), joint pain, constipation, weight increase*, diarrhoea, flatulence.

* Common in combination with thiazolidinediones (another class of medicine used to treat diabetes).

Tell your doctor if any of these symptoms affect you.

Rare (affecting 1 to 10 in 10,000 users)

In rare cases treatment with Galvus, especially in combination with an ACE inhibitor (a medicine used to lower blood pressure), may lead to breathing and swallowing difficulties, swelling of the face, arms and legs, eyes, lips or tongue. If you experience these symptoms, you should stop treatment immediately and inform your doctor.

Very rare (affecting fewer than 1 in 10,000 users)

Upper respiratory tract infection, inflammation of the nasopharynx (nasopharyngitis).

If you experience jaundice or other possible signs of a liver function disorder (yellow eyes and skin, nausea, loss of appetite or dark urine) or severe, continuous abdominal pain (possible sign of an inflamed pancreas), you should stop treatment immediately and contact your doctor.

Contact your doctor immediately if you experience muscle pain, muscle sensitivity or muscle weakness. This is because,

in rare cases, muscle problems may be serious, including muscle breakdown (rhabdomyolysis), which may lead to kidney damage and then death. This risk of muscle breakdown (rhabdomyolysis) may be higher in elderly patients (65 years of age and above), female patients, patients with kidney function problems, patients with thyroid problems and patients taking higher doses of Galvus. The following additional undesired drug reactions have been reported since Galvus was introduced to the market (frequency not known): itchy rash (hives), peeling skin or skin blisters, inflammation of the pancreas (if you experience severe, continuous abdominal pain with or without vomiting, you should stop treatment with Galvus and consult your doctor immediately).

If you notice any side effects, contact your doctor or pharmacist. This also applies particularly to side effects not listed in this leaflet.

Further information

Do not use after the expiry date (= EXP) printed on the pack.

Storage instructions

Keep out of the reach of children. Store in the original pack and protect from moisture. Do not store above 30°C.

Additional information

Your doctor or pharmacist will be able to give you more information. They have access to the detailed prescribing information.

What Galvus contains

Active substances

1 tablet contains 50 mg vildagliptin as the active substance.

Other ingredients

Lactose, microcrystalline cellulose, sodium starch glycolate (type A), magnesium stearate.

Availability/pack sizes

Available only in pharmacies with a doctor's prescription.

50 mg tablets: 28, 112.

Not all pack sizes maybe marketed

Manufacturer

See folding box

This package leaflet was last reviewed by the Swiss Agency for Therapeutic Products (Swissmedic) in July 2021.

® = registered trademark

Novartis Pharma AG, Basle, Switzerland

This is a medicament

- A medicament is a product, which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.

- Do not repeat the same prescription without consulting your doctor.

Keep medicaments out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists