NOVARTIS

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

GALVUS® 50 mg Tablets

Composition:

Each tablet contains: Vildagliptin 50 mg

Inactive ingredients: see section 6 "Further information" and section 2 "Important information about some of the ingredients of the medicine".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Galvus is indicated as an adjunct to diet and exercise in patients with type 2 diabetes mellitus.

- As monotherapy, if diet and exercise are not sufficient, or
- In combination with metformin or a sulfonylurea, if treatment with these preparations does not offer sufficient control of blood glucose levels.

As a triple oral therapy in combination with:

- a sulfonylurea and metformin, when treatment combining diet and exercise with two preparations do not provide adequate glycemic control.

Galvus is also indicated for use in combination with insulin (with or without metformin), when diet and exercise, plus a stable dosage of insulin do not provide adequate glycemic control.

Galvus is indicated as an adjunct to diet and exercise in patients with type 2 diabetes mellitus:

- In combination with a thiazolidinedione, in patients with insufficient glycaemic control and for whom the use of a thiazolidinedione is appropriate.

Therapeutic group:

Medicines used to treat diabetes: Dipeptidyl peptidase 4 (DPP-4) enzyme inhibitors.

Galvus is a medicine to be taken orally, intended to help regulate blood sugar levels.

Type 2 diabetes develops when the pancreas does not secrete enough insulin or when the secreted insulin does not work properly or when the pancreas produces too much glucagon.

Insulin helps to lower the level of sugar in the blood, especially after meals.

Glucagon triggers the production of sugar by the liver, and causes the blood sugar level to rise. The pancreas produces both substances, glucagon and insulin. Galvus activity causes the pancreas to produce more insulin and to reduce the production of glucagon, thereby helping to control the blood sugar level.

The medicine has been shown to lower blood sugar levels, which can help prevent diabetes complications.

Although you are currently starting medicinal treatment for diabetes, it is important that you continue to follow the diet and/or exercise that has been recommended for you.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are allergic to vildagliptin or to any of the additional ingredients contained in the medicine (see section 6 "Further information"). If you think you may be allergic to vildagliptin or any of the ingredients of Galvus, do not take the medicine and talk to the doctor.
- Do not use Galvus if you are pregnant or breastfeeding.

Special warnings regarding use of this medicine:

Before treatment with Galvus, tell the doctor if:

- you have type 1 diabetes (a condition in which your body does not produce insulin) or if you are suffering from diabetic ketoacidosis
- you are taking an anti-diabetes medicine from the sulfonylurea group (your doctor may want to lower the dose of the sulfonylurea when given together with Galvus, in order to prevent a low blood glucose level [hypoglycemia])
- you have moderate or severe kidney disease (you will need to take a low dose of Galvus)
- you are undergoing dialysis treatment
- you have a liver disease
- you suffer from heart failure
- you have or have had a disease of the pancreas.

If you ever had to stop taking a medicine containing vildagliptin because of liver problems, do not resume use of the medicine.

Skin lesions are a common complication of diabetes. It is advisable to follow the doctor's or nurse's recommendations for skin and foot care. It is also advised to pay particular attention to new onset of blisters or ulcers while taking Galvus. Should these occur, you should promptly consult the doctor.

Children and adolescents:

Use of Galvus in children and adolescents up to the age of 18 is not recommended.

Tests and follow-up:

You will undergo a liver function test before treatment with Galvus. During the first year of treatment, you will undergo a liver function test every 3 months, and periodically thereafter. This is to allow for the earliest detection possible of signs of increased liver enzymes.

Drug interactions:

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if you are taking:

- thiazides or other diuretics
- corticosteroids (generally used to treat inflammation)
- thyroid medicines
- certain medicines that affect the nervous system

Use of the medicine and food:

Galvus can be taken with or without a meal.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you are pregnant or are planning to become pregnant, consult with the doctor or pharmacist before taking the medicine.

Do not use Galvus during pregnancy.

It is not known whether Galvus passes into breast milk. Do not use Galvus if you are breastfeeding or plan to breastfeed.

Driving and operating machinery:

If you feel dizzy while taking Galvus, avoid driving and operating machinery.

Important information about some of the ingredients of the medicine:

Galvus contains lactose (milk sugar); each tablet contains 47.82 mg lactose.

If you have been told by the doctor that you have an intolerance to certain sugars, refer to the doctor before taking the medicine.

Galvus contains sodium. This medicine contains less than 1 mmol sodium (23 mg) per tablet, and is therefore considered to be 'sodium free'.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions.

Depending on your response to the treatment, the doctor may increase or lower the dosage of the medicine.

Check with the doctor or pharmacist if you are uncertain regarding the dosage and treatment regimen with Galvus.

The dosage and treatment regimen will be determined by the doctor only.

The usual dosage of Galvus is generally either 50 or 100 mg per day:

- if you are taking Galvus alone, the usual dosage is 50 mg per day, taken as one dose in the morning, or 100 mg per day, taken as a 50 mg dose in the morning and 50 mg in the evening
- if you are taking Galvus in combination with another medicine containing a sulfonylurea, the usual dosage is 50 mg per day, taken as one dose in the morning
- if you are taking Galvus in combination with another medicine containing metformin or glitazone, in combination with metformin and a sulfonylurea, or with insulin (with/without metformin), the usual dosage is 100 mg per day, taken as a 50 mg dose in the morning and 50 mg in the evening

Do not exceed the recommended dosage.

Duration of treatment -

- Take Galvus every day as long as your doctor tells you to. The treatment may be prolonged.
- The doctor will check your condition regularly to confirm that the treatment is having the desired effect.

Method of administration -

Do not chew! Swallow the tablet whole with a glass of water.

Galvus can be taken with or without a meal.

If the doctor has told you to take the medicine once a day – take it in the morning.

If you accidentally took a higher dosage, refer to your doctor immediately. If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or to a hospital emergency room, and bring the package of the medicine with you.

If you forgot to take the medicine, take a dose as soon as you remember. Take the next dose at the scheduled time. However, if it is almost time for the next dose, skip the forgotten dose. Do not take a double dose; consult the doctor.

Adhere to the treatment regimen as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

If you stop taking the medicine

Do not stop taking Galvus unless the doctor has told you to do so. If you have questions regarding the duration of treatment with the medicine, refer to your doctor.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Galvus may cause side effects in some users. Do not be alarmed by the side effects list. You may not suffer from any of them.

Stop taking the medicine and refer to the doctor immediately if you have one or more of the following effects:

- Angioedema (rare: effects that occur in 1-10 in 10,000 users): symptoms include swelling of the face, tongue or throat, swallowing difficulties, breathing difficulties, sudden onset of rash or hives (symptoms of a severe and rare allergic reaction called 'angioedema').
- Liver disease (hepatitis) (unknown frequency): symptoms include yellowing of the skin and eyes, nausea, loss of appetite, dark urine, symptoms indicative of liver diseases (jaundice).
- Inflammation of the pancreas (pancreatitis) (rare: effects that occur in 1-10 in 10,000 users): symptoms include severe and persistent pain in the abdominal area, which might radiate to the back, as well as nausea and vomiting.

Other side effects:

Possible side effects while taking Galvus:

Very common side effects (effects that occur in more than 1 in 10 user): sore throat, runny nose, fever.

Common side effects (effects that occur in 1-10 in 100 users): itchy rash, trembling, headache, dizziness, muscle pains, joint pains, constipation, swelling of the hands, ankles or feet (edema), excessive sweating, vomiting, pain in and around the stomach (abdominal pain), diarrhea, heartburn, nausea, blurred vision.

Uncommon side effects (effects that occur in 1-10 in 1,000 users): weight increase, chills, weakness, sexual dysfunction, low blood glucose level, flatulence.

Rare side effects (effects that occur in 1-10 in 10,000 users): inflammation of the pancreas.

Since this product has been marketed, the following side effects have been reported at unknown frequency (cannot be estimated from the existing data): localized peeling of skin or blisters, blood vessel inflammation (vasculitis) which may result in skin rash or raised, flat, red and round spots under the skin surface or bruising.

If a side effect occurs, if any of the side effects worsen, or when you suffer from a side effect not mentioned in the leaflet, consult the doctor.

Reporting of side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il), that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

Storage conditions:

Store below 30°C. Protect from moisture.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Microcrystalline cellulose, Lactose anhydrous, Sodium starch glycolate, Magnesium stearate.

What the medicine looks like and the content of the package:

A white to light yellowish, round, flat-faced and beveled-edge tablet. One side is debossed with "NVR", and the other side with "FB".

Pack size: 56 tablets.

Registration Holder and Importer and its address:

Novartis Israel Ltd., P.O.B 7126, Tel Aviv.

Revised in September 2022 according to MOH guidelines

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

139 87 31692

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