NOVARTIS

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.

Galvusmet®

What Galvusmet is and what it is used for

This medicine is used on prescription from your doctor.
Galvusmet is a medicine used to treat type 2 diabetes (diabetes mellitus) that is taken by mouth. Galvusmet contains the active substances vildagliptin and metformin. It is prescribed together with diet and exercise to patients who have already received treatment with vildagliptin and metformin or whose diabetes is not adequately controlled with metformin or vildagliptin alone.
To control your blood sugar level, your doctor can prescribe either treatment with Galvusmet alone or together with another oral antidiabetic medicine.
Galvusmet is also prescribed as an additional treatment to insulin, together with diet and exercise, to improve control of blood sugar when a stable dose of insulin and metformin alone does not provide adequate blood sugar control.
Galvusmet helps to control blood sugar levels. Such medicines are known as oral antidiabetics.
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 (produced by the pancreas) helps to decrease blood sugar levels, especially after meals. Glucagon, which is also produced by the pancreas, stimulates sugar production, which increases blood sugar levels.
Galvusmet makes the pancreas produce more insulin and less glucagon (effect of vildagliptin) and helps it to make better use of insulin (effect of metformin). This is how Galvusmet helps to control blood sugar levels.
It is important to follow the recommendations regarding your diet and/or physical exercise during your treatment with Galvusmet.

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 Galvusmet

Do not take Galvusmet:
- If you are allergic to any of its ingredients.
- If you have severely reduced kidney function.
- If you have recently had a heart attack, have heart failure or serious blood circulation disorders, including shock, or have breathing difficulties.
- If you have or have had serious complications relating to your diabetes. This includes diabetic ketoacidosis (a complication of diabetes involving rapid weight loss, nausea and vomiting) or a diabetic coma.
- If you are going to have a contrast X-ray (a special X-ray involving the injection of a dye). In this case you must stop treatment with Galvusmet, either before your X-ray or on the day of your X-ray and for a few days afterwards.

Warnings and precautions

If you become dizzy, you should not drive or use machines.
You should not take Galvusmet if you suffer from a liver disorder or type 1 diabetes. Galvusmet is not a substitute for insulin.
If one or more of the following symptoms occur: feeling cold and uncomfortable, muscle pain, light-headedness, severe nausea or severe vomiting, abdominal pain, dizziness, heart rhythm disorders or rapid breathing. This may be a sign of lactic acidosis, a severe disturbance of the metabolism. In this case you must contact your doctor immediately. Patients with a kidney function disorder are more likely to experience lactic acidosis.
If you experience nausea, sweating, weakness, dizziness, trembling or headaches (signs of a low blood sugar level). This may be due to a lack of food, too much physical activity without sufficient food intake or excessive alcohol consumption.
If you experience any of these symptoms, stop taking Galvusmet and consult a doctor immediately.
If you take Galvusmet 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 Galvusmet. Pancreatitis is a serious, potentially life-threatening illness. Stop taking Galvusmet and consult your doctor if you experience severe, continuous abdominal pain with or without vomiting, as you may be suffering from pancreatitis.
If you are going to have an operation under a general anaesthetic, treatment with Galvusmet must be stopped for a few days before and after the operation. Your doctor will decide when you should stop treatment with Galvusmet and when you should restart treatment.
Galvusmet should only be used in older patients if they do not have reduced kidney function. If you are an older patient, your doctor will check your kidney function several times a year.
No information is available on the use of Galvusmet in children and adolescents (younger than 18 years of age). Galvusmet is therefore not recommended for use in these patients.
If you consume alcohol excessively, either daily or from time to time.
Do not drink alcohol excessively or take medicines containing alcohol while taking Galvusmet.
Please contact your doctor if your blood sugar levels suddenly worsen, your blood sugar test results are abnormal or you feel ill.
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 Galvusmet and in patients with abnormal kidney function.
If you are taking medicines to treat angina pectoris, HIV infection or a specific type of thyroid cancer (medullary thyroid cancer), tell your doctor.

You should also 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

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

Breast-feeding
It is not known whether the active substances of Galvusmet, vildagliptin and metformin hydrochloride, pass into breast milk. You must not take Galvusmet if you are breast-feeding.
Talk to your doctor.

How to take Galvusmet

Your doctor will tell you at which times of day you should take Galvusmet and how many Galvusmet film-coated tablets to take.
The usual dose is 1 film-coated tablet twice daily.
The maximum daily dose of 1 film-coated tablet twice daily must not be exceeded.
The dose prescribed by your doctor must not be exceeded. Depending on your condition your doctor will either prescribe Galvusmet alone or in combination with other medicines used to treat diabetes.

When and how to take Galvusmet
Taking Galvusmet either with or immediately after food will reduce the chance of an upset stomach.
Galvusmet should be swallowed whole with a glass of water.

How long to take Galvusmet
Take Galvusmet for as long as your doctor has prescribed. Regular check-ups with your doctor are important to ensure that the treatment is having the desired effect.
Do not stop taking Galvusmet unless your doctor expressly tells you to do so.

If you forget to take Galvusmet
It is advisable to take your medicine every day at the same time. However, if you forget to take Galvusmet, take it as soon as you remember. Then take the next dose at the usual time. However, if it is almost time for the next dose, do not take the forgotten dose. Do not take a double dose to make up for the forgotten tablet.

If you take more Galvusmet than you should
If you have accidentally taken too many tablets or if someone else has taken your medicine, inform your doctor immediately. You may need medical attention. Please show your doctor the pack if possible.
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 Galvusmet:

Very common (affects more than 1 in 10 users): Nausea, vomiting, diarrhoea, abdominal pain, loss of appetite.

Common (affects 1 to 10 in 100 users): Dizziness, trembling, metallic taste, chills, heartburn, headache, severe sweating, low blood sugar (hypoglycaemia).

Uncommon (affects 1 to 10 in 1,000 users): Tiredness, swollen hands and feet (peripheral oedema), joint pain, constipation, weakness, weight increase, diarrhoea, flatulence.

Very rare (affects fewer than 1 in 10,000 users): Upper respiratory tract infection, inflammation of the nasopharynx (nasopharyngitis), decrease in vitamin B_{12} absorption, lactic acidosis, liver inflammation, skin reactions such as skin reddening, itching, hives (rash with raised, itchy bumps).

In rare cases treatment with Galvusmet, 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.
If you experience jaundice or other possible signs of a liver function disorder (yellow eyes and skin, nausea, loss of appetite or dark urine), you should stop treatment immediately and contact your doctor.
If you experience symptoms of lactic acidosis such as feeling cold and uncomfortable, muscle pain, light-headedness, severe nausea or severe vomiting, diarrhoea, abdominal pain, unexplained weight loss, dizziness, heart rhythm disorders or rapid breathing, you must stop treatment immediately and contact your doctor. Lactic acidosis may lead to a coma.
If you experience severe, continuous abdominal pain with or without vomiting (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 as 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 Galvusmet.
The following additional undesired drug reactions have been reported since Galvusmet was introduced to the market (frequency not known): peeling skin or skin blisters, pancreas inflammation.
Tell your doctor if any of these side effects affect you severely.
If you notice any side effects which are not described here, you should inform your doctor or pharmacist.

Further information

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

Storage instructions

Keep out of the reach of children.

Store in the original pack and protect from moisture. Do not store above 30°C.

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

What Galvusmet contains

Each Galvusmet film-coated tablet contains vildagliptin and metformin hydrochloride (as the active substances) and other ingredients.
Three dosage strengths are available:
- Film-coated tablets containing 50 mg vildagliptin and 500 mg metformin hydrochloride.
- Film-coated tablets containing 50 mg vildagliptin and 850 mg metformin hydrochloride.
- Film-coated tablets containing 50 mg vildagliptin and 1000 mg metformin hydrochloride.

Active substances
Vildagliptin and metformin hydrochloride

Other ingredients
50/500 mg film-coated tablets: Hydroxypropylcellulose, magnesium stearate, hypromellose, titanium dioxide (E171), iron oxide yellow (E172), iron oxide red (E172), macrogol 4000, talc
50/850 mg film-coated tablets: Hydroxypropylcellulose, magnesium stearate, hypromellose, titanium dioxide (E171), iron oxide yellow (E172), macrogol 4000, talc
50/1000 mg film-coated tablets: Hydroxypropylcellulose, magnesium stearate, hypromellose, titanium dioxide (E171), iron oxide yellow (E172), macrogol 4000, talc

Availability/pack sizes

Available only in pharmacies with a doctor's prescription.
- 50/500 mg film-coated tablets: Packs containing 60 or 180 film-coated tablets.
- 50/850 mg film-coated tablets: Packs containing 60 or 180 film-coated tablets.
- 50/1000 mg film-coated tablets: Packs containing 60 or 180 film-coated tablets.
- Not all pack sizes are marketed.

Manufacturer

Manufactured by Novartis Pharma Produktions GmbH, Wehr, Germany for Novartis Pharma AG, Basle, Switzerland.

Batch Releaser: Novartis Saglik,. Kurtkoy, Turkey

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

® = registered trademark

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