

Vildagliptin and Metformin fixed combination (50mg/500mg, 50mg/850mg, 50mg/1000mg)

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What Galvus Met is used for

Galvus Met is available as tablets. Each Galvus Met tablet contains two active substances: vildagliptin and metformin hydrochloride. Both substances belong to a group of medicines called “oral antidiabetics”.

Three dosage strengths are available (vildagliptin/metformin hydrochloride) 50 mg/500 mg, 50 mg/850 mg and 50 mg/1,000 mg.

Galvus Met is a medicine used to treat type 2 diabetes. It helps to control the level of sugar in the blood. It is prescribed as an adjunct to diet and exercise to improve control over body sugar levels

- as a first diabetes treatment in patients whose diabetes is not adequately controlled by diet and exercise alone;
- in patients who have already received treatment with vildagliptin and metformin hydrochloride together as separate tablets;
- or whose diabetes is not adequately controlled with metformin hydrochloride or vildagliptin alone, in combination with other medicinal products from the treatment of diabetes, including insulin when these do not provide adequate glycaemic control.

How Galvus Met works

Galvus Met works by making the pancreas produce more insulin and less glucagon (effect of vildagliptin) and also by helping the body to make better use of the insulin it produces (effect of metformin hydrochloride). Galvus Met helps to control the blood sugar level. It is important that you continue to follow the diet and/or exercise

recommended to you while you are on treatment with Galvus Met.

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

Before you use Galvus Met

Follow all of the doctor’s instructions carefully. They may differ from the general information contained in this leaflet.

When you must not use it

- If you are allergic (hypersensitive) to vildagliptin, metformin hydrochloride or to any of the other ingredients of Galvus Met. If you think you may be allergic, ask your doctor for advice.
- If you have severely reduced kidney function (this will be decided by your doctor).
- If you have recently had a heart attack, have heart failure, or if you have serious problems with your blood circulation, including shock, or breathing difficulties.
- If you have lactic acidosis [too much lactic acid in the blood (see “Risk of lactic acidosis” below)] or ketoacidosis. Ketoacidosis is a condition in which substances called ‘ketone bodies’ accumulate in the blood and which can lead to diabetic pre-coma. Symptoms of acidosis may include stomach pain, abnormal breathing and drowsiness (if severe).

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

Before you start use it

Risk of lactic acidosis

Galvus Met may cause a very rare, but very serious side effect called lactic acidosis, particularly if your kidneys are not working properly. The risk of developing lactic acidosis is also increased with uncontrolled diabetes, serious infections, prolonged fasting or alcohol intake, dehydration, liver problems and any medical conditions in which a part of the body has a reduced supply of oxygen (such as acute severe heart disease). If any of the above apply to you, talk to your doctor for further instructions.

Stop taking Galvus Met for a short time if you have a condition that may be associated with dehydration (significant loss of body fluids) such as severe vomiting, diarrhoea, fever, exposure to heat or if you drink less fluid than normal. Talk to your doctor for further instructions.

Stop taking Galvus Met and contact a doctor or the nearest hospital immediately if you experience some of the symptoms of lactic acidosis, as this condition may lead to coma.

Symptoms of lactic acidosis include:

- vomiting
- stomachache (abdominal pain)
- muscle cramps
- a general feeling of not being well with severe tiredness
- difficulty in breathing

Lactic acidosis is a medical emergency and must be treated in a hospital.

Take special care with Galvus Met

Galvus Met is not a substitute for insulin. You should therefore neither receive Galvus Met 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.

Monitoring your Galvus Met treatment

Your doctor should ensure that the following tests are performed:

- Blood and urine tested for sugar regularly
- Check how your kidneys function:
 - at start of treatment
 - at least once a year while you are on treatment
 - more frequently if you are elderly or if you have worsening kidney function
- 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 your treatment with Galvus Met because of liver problems, you should never start taking Galvus Met again.
- General blood test at least once a year
- A check of vitamin B12 levels may also be carried out at least every two to three years

Galvus Met and older people (65 years of age or above)

Your doctor will check how well your kidneys work. You may need more frequent checks if you have kidney problems.

Galvus Met and children and adolescents (below 18 years)

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

Taking other medicines

Tell your doctor or pharmacist or healthcare provider if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription. This is particularly important with the following medicines:

- certain medicines used to treat inflammation (e.g. corticosteroids)
- certain medicines used to treat high blood pressure (e.g. a nifedipine, enalapril, losartan, diuretics)
- certain medicines used to reduce pain (e.g., diclofenac)

- certain medicines used to treat angina (e.g. ranolazine)
- certain medicines used to treat HIV infection (e.g. dolutegravir)
- certain medicines used to treat a specific type of thyroid cancer (medullary thyroid cancer) (e.g. vandetanib)
- certain medicines used to treat stomach disorders (e.g. cimetidine)
- certain medicines used to treat some psychiatric disorders (e.g. phenothiazine)
- certain medicines used to treat thyroid disorders
- oral contraceptives, certain medicines used to reduce symptoms in women experiencing menopause or osteoporosis (e.g. estrogen)

Ask your doctor or pharmacist or healthcare provider if you are not sure whether your medicine is one of the medicines listed above.

How to use Galvus Met

Always take this medicine exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist or healthcare provider if you are not sure. Do not exceed the recommended dose prescribed by your doctor.

How much to use

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

The usual dose of Galvus Met is one or two tablets a day. Do not exceed two tablets a day. Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.

If you have reduced kidney function, your doctor may prescribe a lower dose. Also if you are taking an anti-diabetic medicine known as a sulphonylurea your doctor may prescribe a lower dose. Your doctor will prescribe Galvus Met either alone or in combination with other antidiabetics, depending on your condition.

When to use Galvus Met

Galvus Met should be taken in the morning and/or in the evening. It is recommended that you take your tablets either with or just after taking food. This will reduce the chance of you getting an upset stomach.

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

How long to use Galvus Met

Continue taking Galvus Met 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 Met because of liver problems, you should never start taking Galvus Met again. If you have questions about how long to take Galvus Met, talk to your doctor or your pharmacist or healthcare provider.

If you forget to use Galvus Met

It is recommended to take your medicine at the same time each day. If you forget to take Galvus Met, take it as soon as you remember. Then take your next dose at its 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 Galvus Met tablets, or if someone else has taken your medicine, talk to a doctor straight away. You may need medical attention. Show the doctor the pack if possible.

While you are using Galvus Met

Things you must do

- If you experience one or more of the following symptoms: feeling cold and uncomfortable, muscle pain, drowsiness, severe nausea or vomiting, abdominal pain, dizziness, irregular heartbeat, or rapid breathing. Very rarely, patients taking metformin (one of the active substances of Galvus Met) have experienced a condition called lactic acidosis (too much lactic acid in the blood). This is more likely to occur in patients whose kidneys are not working properly.
- If you experience nausea, sweating, weakness, dizziness, trembling, headache (signs of low blood sugar), which could be due to lack of food, too strenuous exercise without sufficient food intake, or excessive

alcohol intake (usually not with Galvus Met alone).

- If your diabetes worsens suddenly, or if you have abnormal blood sugar tests or feel ill, contact your doctor.

If any of these apply to you, tell your doctor or pharmacist or healthcare provider immediately.

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 drink alcohol excessively or take medicines that contain alcohol while taking Galvus Met tablets.

Do not give Galvus Met to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

- If you are going to have an operation under general anesthetic, you must stop taking Galvus Met for a couple of days before and after the procedure. Your doctor will decide when you must stop and when to restart your treatment with Galvus Met.
- If you are going to have a contrast x-ray (a specific type of x-ray involving an injectable dye), you must stop taking Galvus Met before or at the time of and for a few days after the procedure.
- If you are taking any medicines to treat angina or HIV infection or thyroid cancer (medullary thyroid cancer).
- If you drink alcohol excessively, either every day or only from time to time.
- If you have liver or kidney problems.

If you any of these apply to you, tell your doctor or pharmacist or healthcare provider before taking Galvus Met .

Side effects

Like all medicines, Galvus Met can cause side effects, although not everybody gets them.

Some side effects could be serious

STOP taking Galvus Met and seek medical help immediately if you have experience any of the following:

- Feeling cold and uncomfortable, muscle pain, drowsiness, severe nausea or vomiting, abdominal pain, unexplained weight loss, dizziness, irregular heartbeat, or rapid breathing (symptoms of lactic acidosis). If this happens you must stop taking Galvus Met and contact a doctor or the nearest hospital immediately, as lactic acidosis may lead to coma.
- 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 urine (possible symptoms of liver problems).
- Severe upper stomach pain (possible symptoms of inflamed pancreas).
- Headache, drowsiness, weakness, dizziness, confusion, irritability, hunger, fast heartbeat, sweating, feeling jittery (possible symptoms of low level of sugar in the blood known as hypoglycemia)

If you experience any serious side effects, stop taking this medicine and tell your doctor immediately.

Very common: may affect more than 1 in 10 people

- Nausea, vomiting, diarrhea, abdominal pain, loss of appetite.

Common: may affect up to 1 in every 10 people

- Dizziness, headache, trembling, metallic taste in the mouth.

Uncommon: may affect up to 1 in every 100 people

- Constipation, swollen hands, ankles or feet (edema).

Very rare: may affect up to 1 in every 10,000 people

- Skin reddening, itching, decrease in the level of vitamin B12 in the blood, abnormal liver function test results.

If you experience any serious side effects, stop taking this medicine and tell your doctor immediately.

Other possible side effects

Other side effects include the following listed below. If these side effects become severe, please tell your doctor, pharmacist or healthcare provider.

Common side effects (likely to occur in fewer 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 Met and insulin:

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

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

- Common: Dizziness, trembling, weakness, excessive sweating.

Some patients have experienced other side effects while taking Galvus Met alone or in combination with another antidiabetic medication:

- Itchy rash, areas of peeling skin or blisters, joint pain.

If you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist or healthcare provider.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumer →Reporting Side Effects to Medicines (ConSERF) or Vaccines(AEFI)].

Storage and Disposal of Galvus Met

Storage

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

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

Galvus Met is supplied as tablets. Three dosage strengths are available and the physical description of Galvus Met tablets is as follows:

- 50 mg/500 mg: light yellow, ovaloid beveled edge, film-coated tablet imprinted with "NVR" on one side and "LLO" on the other side.
- 50 mg/850 mg: yellow, ovaloid beveled edge, film-coated tablet imprinted with "NVR" on one side and "SEH" on the other side.
- 50 mg/1,000 mg: dark yellow, ovaloid beveled edge, film-coated tablet imprinted with "NVR" on one side and "FLO" on the other side

Ingredients

- *Active ingredients*

The active substances of Galvus Met are vildagliptin and metformin hydrochloride.

- *Inactive ingredients*

The other ingredients (excipients) of Galvus Met are hydroxypropyl cellulose, hypromellose, iron oxide yellow, iron oxide red, macrogol, magnesium stearate, talc and titanium dioxide.

MAL number:

MAL14125131ARZ (50/500 MG)

MAL14125129ARZ (50/850 MG)

MAL14125130ARZ(50/1000 MG)

Manufacturer

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Product Registration Holder

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