

GALVUS[®] MET

Vildagliptin and Metformin fixed Combination

50 mg/500 mg, 50 mg/850 mg, 50 mg/1,000 mg Tablets

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What Galvus Met is used for

Galvus Met is available as tablets. Each tablet of Galvus Met 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 is prescribed together with diet and exercise in patients who have already received treatment with vildagliptin and metformin hydrochloride together, or whose diabetes is not adequately controlled with metformin hydrochloride or vildagliptin alone.

Galvus Met helps to control the level of sugar in the blood.

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 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 advised for you whilst 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 instructions given to you by your doctor or pharmacist carefully, even if they differ from the information contained in this leaflet.

When you must not use it:

- If you are allergic (hypersensitive) to vildagliptin, metformin hydrochloride or any of the other ingredients of Galvus Met.
- If you have a problem with your kidneys.
- If you have recently had a heart attack, have a heart failure, or if you have severe circulatory problems, including shock, or breathing difficulties.
- If you have or have had serious complications of your diabetes, such as diabetic ketoacidosis (a complication of diabetes involving rapid weight loss, nausea or vomiting) or diabetic coma.
- If you are going to have a contrast x-ray (a specific type of x-ray involving an injectable dye). You will need to temporarily stop taking Galvus Met at the time of and for a few days after the procedure.

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 to use it

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.
- Patients with hepatic impairment, including patients with a pre-treatment ALT or AST >2.5X the upper limit of normal should not be treated with Galvus Met.

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 whilst you are on treatment
 - more often if you are elderly
- Check how your liver functions:
 - at start of treatment
 - every 3 months during the first year of treatment and regularly thereafter

- if your doctor told you to stop your treatment with Eucreas because of liver problems you should never start taking Eucreas 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

Galvus Met should only be used in elderly patients if they do not have any kidney problems. Your doctor should check the function of your kidneys several times a year if you are elderly.

Galvus Met and children

There is no information available on the use of Eucreas in children (age less than 18 years). The use of Galvus Met in these patients is therefore not recommended.

Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. Remember also those not prescribed by a doctor. 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. diuretics)
- certain medicines used to treat irregular heartbeat (e.g. digoxin)
- certain medicines used to treat stomach disorders (e.g. cimetidine)
- certain medicines used to treat thyroid disorders

Do not drink alcohol excessively or take medicines that contain alcohol whilst taking Eucreas tablets.

How to use Galvus Met

Follow all instructions given to you by your doctor and pharmacist carefully, even if they differ from the ones given in this leaflet. Do not take more Galvus Met than your doctor has prescribed.

How much to use

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

Galvus Met may be initiated at either the 50 mg/500 mg, 50 mg/850 mg or 50 mg/1000 mg tablet strength twice daily, one tablet in the morning and the other in the evening. The recommended daily dose is 100 mg vildagliptin plus 2000 mg metformin hydrochloride. Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.

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 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 told you to stop your 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.

If you forget to use Galvus Met

It is advisable to take your medicine at the same time each day. If you forget to take Galvus Met, take it as soon as you remember and 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 tablets, or if someone else has taken your medicine, talk to a doctor straight away. You may

require medical attention. Show the doctor the pack if possible.

While you are using Galvus Met

Things you must do

- If you are going to have an operation under general anaesthetic, you may need to stop taking Eucreas for a couple of days before and after the procedure.
- If you drink alcohol excessively, either every day or only from time to time.
- If you have a liver disease.
- If your diabetes control 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.

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 give *Galvus Met* to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

- 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 Eucreas) 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 level of sugar (glucose) in the blood) which could be due to lack of food, too strenuous exercise without sufficient food intake, excessive alcohol intake (usually not with Galvus Met alone).

If you experience some of these symptoms, stop taking Galvus Met and consult a doctor immediately.

Driving and using machines

If you feel dizzy while taking Galvus Met, do not drive vehicles or use any tools or machines until you are feeling normal again.

Side effects

Galvus Met can have some side effects in some people. Some patients have experienced the following side effects whilst taking Galvus Met.

Some side effects could be serious

You should stop taking Galvus Met and see your doctor immediately if you experience the following symptoms:

- 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).
- 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 eyes, nausea, loss of appetite, dark urine (possible symptoms of liver problems).

If you experience any of these, tell your doctor straight away.

Some side effects are very common (likely to occur in more than 1 in 10 patients)

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

If any of these affects you severely, tell your doctor.

Some side effects are common (likely to occur in fewer than 1 in 10 patients)

- Dizziness, headache, involuntary trembling, metallic taste.

If any of these affects you severely, tell your doctor.

Some side effects are uncommon (likely to occur in fewer than 1 in 100 patients)

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

If any of these affects you severely, tell your doctor.

Some side effects are very rare (likely to occur in fewer than 1 in 10,000 patients)

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

If any of these affects you severely, tell your doctor.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers →Reporting).

Storage and disposal of Galvus Met

Storage

- 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.
- Keep out of the reach and sight of children.

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 available as tablets. Three dosage strengths are available:

- Galvus Met 50/500MG Film Coated Tablet: Light yellow, ovaloid beveled edge, film-coated tablet imprinted with "NVR" on one side and "LLO" on the other side.
- Galvus Met 50/850MG Film-Coated Tablet: Yellow,

ovaloid beveled edges, film coated tablet imprinted (debossed) with “NVR” on one side and “SEH” on the other side.

- Galvus Met 50/1000MG Film-Coated Tablet: Dark yellow, ovaloid beveled edge, film coated tablet imprinted (debossed) with “NVR” on one side and “FLO” on the other side.

Ingredients:

Active Ingredients

Each tablet of Galvus Met contains two active substances: vildagliptin and metformin hydrochloride.

Inactive Ingredients

The other ingredients are: Ferric oxide red, ferric oxide yellow, hypromellose, hydroxypropylcellulose, magnesium stearate, polyethylene glycol, and talc.

MAL Number:

Galvus Met 50/500MG Film coated tablet: MAL12035005A

Galvus Met 50/850MG Film coated tablet: MAL20091864A

Galvus Met 50/1000MG Film coated tablet: MAL20091865AR

Manufacturer

Novartis Pharma Stein AG, Schaffhauserstrasse, CH-4332, Stein, Switzerland

Product Registration Holder

Novartis Corporation (Malaysia) Sdn. Bhd. Level 22, Tower B, Plaza 33, No. 1, Jalan Kemajuan, Seksyen 13, 46100 Petaling Jaya

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