

PACKAGE LEAFLET

Package leaflet: Information for the user
Vildagliptine Hetero 50 mg tabletten
Vildagliptin

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Vildagliptine Hetero is and what it is used for
2. What you need to know before you take Vildagliptine Hetero
3. How to take Vildagliptine Hetero
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1. What Vildagliptine Hetero is and what it is used for

The active substance of Vildagliptine Hetero, vildagliptin, belongs to a group of medicines called “oral antidiabetics”.

Vildagliptine Hetero is used to treat adult patients with type 2 diabetes. It is used when diabetes cannot be controlled by diet and exercise alone. It helps to control the level of sugar in the blood. Your doctor will prescribe Vildagliptine Hetero either alone or together with certain other antidiabetic medicines which you will already be taking, if these have not proved sufficiently effective to control diabetes.

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 Vildagliptine Hetero works

Vildagliptine Hetero works by making the pancreas produce more insulin and less glucagon. This helps to control the blood sugar level. This medicine has been shown to reduce blood sugar, which may help to prevent complications from your diabetes. Even though you are now starting a medicine for your diabetes, it is important that you continue to follow the diet and/or exercise which has been recommended for you.

2. What you need to know before you take Vildagliptine Hetero

Do not take Vildagliptine Hetero:

- if you are allergic to vildagliptin or any of the other ingredients of this medicine (listed in section 6). If you think you may be allergic to vildagliptin or any of the other ingredients of Vildagliptine Hetero, do not take this medicine and talk to your doctor.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Vildagliptine Hetero

- if you have type 1 diabetes (i.e. your body does not produce insulin) or if you have a condition called diabetic ketoacidosis.
- if you are taking an anti-diabetic medicine known as a sulphonylurea (your doctor may want to reduce your dose of the sulphonylurea when you take it together with Vildagliptine Hetero in order to avoid low blood glucose [hypoglycaemia]).
- if you have moderate or severe kidney disease (you will need to take a lower dose of Vildagliptine Hetero).
- if you are on dialysis.
- if you have liver disease.
- if you suffer from heart failure.
- if you have or have had a disease of the pancreas.

If you have previously taken vildagliptin but had to stop taking it because of liver disease, you should not take this medicine.

Diabetic skin lesions are a common complication of diabetes. You are advised to follow the recommendations for skin and foot care that you are given by your doctor or nurse. You are also advised to pay particular attention to new onset of blisters or ulcers while taking Vildagliptine Hetero. Should these occur, you should promptly consult your doctor.

A test to determine your liver function will be performed before the start of Vildagliptine Hetero treatment, at three-month intervals for the first year and periodically thereafter. This is so that signs of increased liver enzymes can be detected as early as possible.

Children and adolescents

The use of Vildagliptine Hetero in children and adolescents up to 18 years of age is not recommended.

Other medicines and Vildagliptine Hetero

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Your doctor may wish to alter your dose of Vildagliptine Hetero if you are taking other medicines such as:

- thiazides or other diuretics (also called water tablets)
- corticosteroids (generally used to treat inflammation)
- thyroid medicines
- certain medicines affecting the nervous system.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You should not use Vildagliptine Hetero during pregnancy. It is not known if Vildagliptine Hetero passes into breast milk. You should not use Vildagliptine Hetero if you are breast-feeding or plan to breast-feed.

Driving and using machines

If you feel dizzy while taking Vildagliptine Hetero, do not drive or use machines.

Vildagliptine Hetero contains lactose

Vildagliptine Hetero contains lactose (milk sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Vildagliptine Hetero contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Vildagliptine Hetero

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

How much to take and when

The amount of Vildagliptine Hetero people have to take varies depending on their condition. Your doctor will tell you exactly how many tablets of Vildagliptine Hetero to take. The maximum daily dose is 100 mg.

The usual dose of Vildagliptine Hetero is either:

- 50 mg daily taken as one dose in the morning if you are taking Vildagliptine Hetero with another medicine called a sulphonylurea.
- 100 mg daily taken as 50 mg in the morning and 50 mg in the evening if you are taking Vildagliptine Hetero alone, with another medicine called metformin or a glitazone, with a combination of metformin and a sulphonylurea, or with insulin.
- 50 mg daily in the morning if you have moderate or severe kidney disease or if you are on dialysis.

How to take Vildagliptine Hetero

- Swallow the tablets whole with some water.

How long to take Vildagliptine Hetero

- Take Vildagliptine Hetero every day for as long as your doctor tells you. You may have to take this treatment over a long period of time.
- Your doctor will regularly monitor your condition to check that the treatment is having the desired effect.

If you take more Vildagliptine Hetero than you should

If you take too many Vildagliptine Hetero tablets, or if someone else has taken your medicine, **talk to your doctor straight away**. Medical attention may be needed. If you need to see a doctor or go to the hospital, take the pack with you.

If you forget to take Vildagliptine Hetero

If you forget to take a dose of this medicine, take it as soon as you remember. Then take your next dose at the usual time. If it is almost time for your next dose, skip the dose you missed. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Vildagliptine Hetero

Do not stop taking Vildagliptine Hetero unless your doctor tells you to. If you have questions about how long to take this medicine, talk to your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some symptoms need immediate medical attention:

You should stop taking Vildagliptine Hetero and see your doctor immediately if you experience the following side effects:

- Angioedema (rare: may affect up to 1 in 1,000 people): Symptoms include swollen face, tongue or throat, difficulty swallowing, difficulties breathing, sudden onset rash or hives, which may indicate a reaction called “angioedema”.
- Liver disease (hepatitis) (rare): Symptoms include yellow skin and eyes, nausea, loss of appetite or dark-coloured urine, which may indicate liver disease (hepatitis).

- Inflammation of the pancreas (pancreatitis) (frequency not known): Symptoms include severe and persistent pain in the abdomen (stomach area), which might reach through to your back, as well as nausea and vomiting.

Other side effects

Some patients have had the following side effects while taking vildagliptin and metformin:

- Common (may affect up to 1 in 10 people): Trembling, headache, dizziness, nausea, low blood glucose
- Uncommon (may affect up to 1 in 100 people): Tiredness

Some patients have had the following side effects while taking vildagliptin and a sulphonylurea:

- Common: Trembling, headache, dizziness, weakness, low blood glucose
- Uncommon: Constipation
- Very rare (may affect up to 1 in 10,000 people): Sore throat, runny nose

Some patients have had the following side effects while taking vildagliptin and a glitazone:

- Common: Weight increase, swollen hands, ankle or feet (oedema)
- Uncommon: Headache, weakness, low blood glucose

Some patients have had the following side effects while taking vildagliptin alone:

- Common: Dizziness
- Uncommon: Headache, constipation, swollen hands, ankle or feet (oedema), joint pain, low blood glucose
- Very rare: Sore throat, runny nose, fever

Some patients have had the following side effects while taking vildagliptin, metformin and a sulphonylurea:

- Common: Dizziness, tremor, weakness, low blood glucose, excessive sweating

Some patients have had the following side effects while taking vildagliptin and insulin (with or without metformin):

- Common: Headache, chills, nausea (feeling sick), low blood glucose, heartburn
- Uncommon: Diarrhoea, flatulence

Since this product has been marketed, the following side effects have also been reported:

- Frequency not known (cannot be estimated from the available data): Itchy rash, inflammation of the pancreas, localised peeling of skin or blisters, muscle pain

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting Netherlands Bijwerkingen Centrum Lareb. Website: www.lareb.nl. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Vildagliptine Hetero

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the blister and the carton after "EXP". The expiry date refers to the last day of that month.
- Blister: store in the original package in order to protect from moisture.
- Bottle: keep the bottle tightly closed in order to protect from moisture.
- Do not use any Vildagliptine Hetero pack that is damaged or shows signs of tampering.

6. Contents of the pack and other information

What Vildagliptine Hetero contains

- The active substance is vildagliptin.
Each tablet contains 50 mg vildagliptin.
- The other ingredients are microcrystalline cellulose (E460), lactose anhydrous, sodium starch glycolate (type A) and magnesium stearate (E470b).

What Vildagliptine Hetero looks like and contents of the pack

Vildagliptine Hetero 50 mg tablets are round, white to off-white, with “V12” on one side and “H” on the other.

Vildagliptine Hetero 50 mg tablets are available in blister packs containing 7, 14, 28, 30, 56, 60, 90, 112, 180 or 336 tablets and in multipacks comprising 3 cartons, each containing 112 tablets and in HDPE bottles containing 100 tablets.

Not all pack sizes may be marketed in your country.

Marketing Authorisation Holder

Hetero Europe S.L.
Viladecans Business Park – Edificio Australia
Antonio Machado 78-80
08840 Viladecans (Barcelona)
Spanje

Manufacturer

Pharmadox Healthcare Ltd
KW20A Kordin Industrial Park
Paola, PLA 3000
Malta

In het register ingeschreven onder: RVG 124509

This medicinal product is authorised in the Member States of the EEA under the following names:

Duitsland	Vildagliptin Hetero 50 mg tabletten;
Nederland	Vildagliptine Hetero 50 mg tabletten
Spanje	Vildagliptina Hetero 50 mg comprimidos EFG

This leaflet was last revised in oktober 2022

Detailed information on this medicine is available on the website of {name of MS Agency (link)}