

Package leaflet: Information for the user

Vildagliptin STADA 50 mg tablets

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

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2. What you need to know before you take Vildagliptin STADA
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1. What Vildagliptin STADA 50 mg tablets are and what they are used for

The active substance of Vildagliptin STADA 50 mg tablets, vildagliptin, belongs to a group of medicines called “oral antidiabetics”.

Vildagliptin STADA 50 mg tablets are 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 your blood. Your doctor will prescribe Vildagliptin STADA either alone or together with certain other antidiabetic medicines which you will already be taking, if these have not been sufficiently effective in controlling your 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 a rise in blood sugar levels. The pancreas makes both of these substances.

How Vildagliptin STADA works

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

2. What you need to know before you take Vildagliptin STADA 50 mg tablets

DO NOT take Vildagliptin STADA

- if you are allergic to vildagliptin or any of the other ingredients of this medicine (listed in section 6)

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Vildagliptin STADA if you:

- have type 1 diabetes (i.e. your body does not produce insulin) or if you have a condition called diabetic ketoacidosis
- 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 this medicine in order to avoid low blood glucose [hypoglycaemia])
- have moderate or severe kidney disease (you will need to take a lower dose of Vildagliptin STADA)
- are on dialysis
- have liver disease
- suffer from heart failure
- 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 blisters or ulcers while taking this medicine. Should these occur, you should consult your doctor promptly.

A test to assess your liver function will be performed before the start of treatment with Vildagliptin STADA, 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 Vildagliptin STADA in children and adolescents up to 18 years of age is not recommended.

Other medicines and Vildagliptin STADA

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 Vildagliptin STADA 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 take this medicine during pregnancy.

It is not known if Vildagliptin STADA passes into breast milk. You should not take Vildagliptin STADA if you are breast-feeding or plan to breast-feed.

Driving and using machines

If you feel dizzy while taking Vildagliptin STADA, do not drive or use machines.

Vildagliptin STADA 50 mg tablets contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your

doctor before taking this medicine.

Vildagliptin STADA 50 mg tablets contain sodium

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

3. How to take Vildagliptin STADA 50 mg tablets

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

Dosage

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

The usual dose of Vildagliptin STADA is either:

- 50 mg daily taken as one dose in the morning if you are taking Vildagliptin STADA 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 Vildagliptin STADA alone, with another medicine called metformin or a glitazone, with a combination of metformin and a sulphonylurea, or with insulin (with or without metformin).
- 50 mg daily in the morning if you have moderate or severe kidney disease or if you are on dialysis.

How to take Vildagliptin STADA

Swallow the tablets whole with some water.

How long to take Vildagliptin STADA for

Take Vildagliptin STADA 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 Vildagliptin STADA than you should

If you take too many Vildagliptin STADA 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 Vildagliptin STADA

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 Vildagliptin STADA

Do not stop taking this medicine unless your doctor tells you to.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

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 Vildagliptin STADA 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
- liver disease (hepatitis) (rare). Symptoms include yellow skin and eyes, nausea, loss of appetite or dark-coloured urine
- 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 medicines containing vildagliptin as a single substance have 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
- liver disease (hepatitis) – usually disappears when treatment is discontinued. Symptoms include yellow skin and eyes, nausea, loss of appetite or dark-coloured urine
- abnormal liver function tests – usually reversible when treatment is discontinued

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 system listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Vildagliptin STADA 50 mg tablets

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.

Store in the blister in order to protect from moisture.

This medicinal product does not require any special temperature storage conditions.

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.

6. Contents of the pack and other information

What Vildagliptin STADA 50 mg tablets contain

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

What Vildagliptin STADA looks like and contents of the pack

Vildagliptin STADA 50 mg tablets are white to light yellowish, round, flat faced, bevelled-edge tablets with 8.0 ± 0.2 mm diameter.

Vildagliptin STADA 50 mg tablets are available in standard & unit dose blisters in cartons of 14, 28, 30, 56, 60, 90, 105, 112, 180 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

[To be completed nationally]

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

[To be completed nationally]

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