

Patient Information Leaflet

SCHEDULING STATUS: S3

VILDAGLIPTIN 50 UNICORN tablets

Vildagliptin 50 mg

Contains sugar: (47,00mg lactose)

Read all of this leaflet carefully before you start taking VILDAGLIPTIN 50 UNICORN

- Keep this leaflet. You may need it to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **VILDAGLIPTIN 50 UNICORN** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What **VILDAGLIPTIN 50 UNICORN** is and what it is used for
2. What you need to know before you take **VILDAGLIPTIN 50 UNICORN**
3. How to take **VILDAGLIPTIN 50 UNICORN**
4. Possible side-effects
5. How to store **VILDAGLIPTIN 50 UNICORN**

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6. Contents of the pack and other information

1. What **VILDAGLIPTIN 50 UNICORN** is and what it is used for

The active substance of **VILDAGLIPTIN 50 UNICORN**, vildagliptin, belongs to a group of medicines called “oral antidiabetics”.

VILGAGLIPTIN 50 UNICORN is used to treat adult patients with type 2 diabetes. It is used as add-on therapy (double-therapy) or triple-therapy in combination with metformin, or insulin (with or without metformin) 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 **VILGAGLIPTIN 50 UNICORN** either alone or together with certain other antidiabetic medicines, such as metformin or insulin, which you will already be taken and if these have not proven to control your diabetes sufficiently and effectively.

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 produced too much glucagon.

Management of diabetes should always include diet control. Caloric restriction, weight loss, and exercise are essential for the proper treatment of the diabetic patient. This is important not only for the primary treatment of diabetes, but also as an adjunct to medicinal therapy

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How VILDAGLIPTIN 50 UNICORN works

VILDAGLIPTIN 50 UNICORN 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 VILDAGLIPTIN 50 UNICORN

Do not take VILDAGLIPTIN 50 UNICORN

- If you are hypersensitive (allergic) to vildagliptin or to any of the excipients of **VILDAGLIPTIN 50 UNICORN** (listed in section 6).
- If you have hepatic impairment (liver disease/deficiency) and your liver is not functioning normally.

Warnings and precautions

Take special care

- if you are taking insulin. **VILDAGLIPTIN 50 UNICORN** is not a substitute for insulin in insulin-requiring patients. **VILDAGLIPTIN 50 UNICORN** should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis (a serious complication of type 1 diabetes that can be life-threatening).

- if you have previously taken vildagliptin but had to stop taking it because of liver disease. You should not take **VILDAGLIPTIN 50 UNICORN**.
- if you have or develop diabetic skin lesions; 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 **VILDAGLIPTIN 50 UNICORN**. Should these occur, you should promptly consult your doctor.

Talk to your doctor, pharmacist or nurse before taking VILDAGLIPTIN 50 UNICORN

- if you suffer from arthralgia (pain in a joints).
- 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 **VILDAGLIPTIN 50 UNICORN**, 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 **VILDAGLIPTIN 50 UNICORN**).
- if you are on dialysis.
- if you have liver disease. A test to determine your liver function will be performed before the start of **VILDAGLIPTIN 50 UNICORN** 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.

- if you suffer from heart failure.
- if you have or have had a disease of the pancreas.

Children and adolescents

The use of **VILDAGLIPTIN 50 UNICORN** in children and adolescents up to 18 years of age is not recommended.

Other medicines and VILDAGLIPTIN 50 UNICORN

Always tell your health care provider if you are taking any other medicine. (This includes all complementary medicines).

Your doctor may wish to alter your dose of **VILDAGLIPTIN 50 UNICORN** 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.

VILDAGLIPTIN 50 UNICORN has no relevant interactions with other oral antidiabetic medicines such as glibenclamide, pioglitazone, metformin, heart medications such as, amlodipine, digoxin, ramipril, simvastatin, valsartan or warfarin.

Pregnancy and breast-feeding and fertility

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If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

You should not use **VILDAGLIPTIN 50 UNICORN** during pregnancy. It is not known if **VILDAGLIPTIN 50 UNICORN** passes into breast milk. You should not use **VILDAGLIPTIN 50 UNICORN** if you are breast-feeding or plan to breast-feed.

Driving and using machines

VILDAGLIPTIN 50 UNICORN may cause dizziness. Patients who experience dizziness as an adverse reaction should avoid driving vehicles or using machines.

VILDAGLIPTIN 50 UNICORN contains lactose. **VILDAGLIPTIN 50 UNICORN** 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 **VILDAGLIPTIN 50 UNICORN**.

3. How to take VILDAGLIPTIN UNICORN

Do not share medicines prescribed for you with any other person.

Always take **VILDAGLIPTIN 50 UNICORN** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Your doctor will tell you how long your treatment with **VILDAGLIPTIN 50 UNICORN** will last.

If you have the impression that the effect of **VILDAGLIPTIN 50 UNICORN** is too strong or too weak, tell your doctor or pharmacist.

The management of antidiabetic therapy should be individualised.

Your doctor will regularly monitor your condition to check that the treatment is having the desired effect.

Swallow the tablets whole with some water.

The recommended dose of **VILDAGLIPTIN 50 UNICORN** is 50 mg a day or 50 mg twice a day in combination with metformin or insulin (with or without metformin).

For triple combination, the recommended dose of **VILDAGLIPTIN 50 UNICORN** is 50 mg twice a day with metformin and a sulphonylurea.

When used in combination with a sulphonylurea, the recommended dose of **VILDAGLIPTIN 50 UNICORN** is 50 mg once daily administered in the morning. In this patient population, vildagliptin 100 mg daily was no more effective than vildagliptin 50 mg once daily.

If you take more VILDAGLIPTIN 50 UNICORN than you should:

If you take too many **VILDAGLIPTIN 50 UNICORN tablets**, or if someone else has taken your medicine, talk to your doctor straight away. In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take VILDAGLIPTIN 50 UNICORN

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 50 UNICORN

Do not stop taking **VILDAGLIPTIN 50 UNICORN** 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:

VILDAGLIPTIN 50 UNICORN can have side effects.

Not all the side effects reported for **VILDAGLIPTIN 50 UNICORN** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

Some symptoms need immediate medical attention

You should stop taking **VILDAGLIPTIN 50 UNICORN** and see your doctor immediately, or go to the casualty department of your nearest hospital, if you experience the following side effects:

- Angioedema: 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): 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): Symptoms include severe and persistent pain in the abdomen (stomach area), which might reach through to your back, as well as nausea and vomiting.

These all are very serious side effects. If you have them, you may have had a serious reaction to VILDAGLIPTIN 50 UNICORN. You may need urgent medical attention or hospitalisation.

Other side effects

Tell your doctor if you notice any of the following:

Frequent

- trembling, dizziness, headache, chills
- weakness (asthenia), swollen hands, ankle or feet (oedema)
- nausea, indigestion / heartburn (reflux), constipation
- low blood glucose

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- sweating

Less frequent

- diarrhoea, bloating (flatulence)

Frequency unknown

- inflammation of the pancreas (pancreatitis)
- itchy rash (urticaria), localised peeling of skin or blisters
- joint pain (arthralgia)
- inflammation of the liver (hepatitis)

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse.

You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website.

Adverse Drug Reactions may also report to Unicorn Pharmaceutical (Pty) Ltd using the following email: vigilance@unicornpharma.co.za

5. How to store VILDAGLIPTIN 50 UNICORN

- Store at or below 25 °C.
- Shelf-life 36 months.
- Do not use after the expiry date on the carton.

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- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What VILDAGLIPTIN 50 UNICORN contains:

- The active substance is vitagliptin.
- Each tablet contains 50 mg vildagliptin.
- The other ingredients are microcrystalline cellulose, lactose, pregelatinised maize starch and magnesium stearate.

What VILDAGLIPTIN 50 UNICORN looks like and contents of the pack:

VILDAGLIPTIN 50 UNICORN are white to off-white, round, flat tablets, engraved with 'VLD' on the one side, plain on the other.

VILDAGLIPTIN 50 UNICORN tablets are packed in aluminium / aluminium blisters of 28 or 56 tablets. The blisters are packed in an outer cardboard box. Not all pack sizes may be marketed.

Holder of Certificate of Registration

Unicorn Pharmaceuticals (Pty) Ltd
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41 Sir Lowry Road
Woodstock, Cape Town, 7925
Product Registration

Unicorn Pharmaceuticals (Pty) Ltd
Dosage form (Strength): Tablet (50 mg)

Product Name: VILDAGLIPTIN 50 UNICORN

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