APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

VIDAMACE 50 mg tablets

Vildagliptin

VIDAMACE 50 mg contains sugar (lactose monohydrate 43,84 mg per tablet)

VIDAMACE 50 mg contains 3,00 mg sodium and is essentially sodium-free

Read all of this leaflet carefully before you start taking VIDAMACE 50 mg

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- VIDAMACE 50 mg 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

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1. What VIDAMACE 50 mg is and what it is used for

The active substance of VIDAMACE 50 mg, vildagliptin, belongs to a group of medicines called "oral antidiabetics".

VIDAMACE 50 mg is used to treat adult patients with type 2 diabetes whose condition cannot be controlled by diet and exercise alone. It helps to control the level of sugar in the blood. Your doctor will prescribe VIDAMACE 50 mg 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.

It is important that you continue to follow the diet and/or exercise advised for you, whilst you are on treatment with VIDAMACE 50 mg.

2. What you need to know before you take VIDAMACE 50 mg

Do not take VIDAMACE 50 mg:

- if you are hypersensitive (allergic) to vildagliptin, or to any of the ingredients of VIDAMACE 50 mg (see section 6)
- if you have liver disease.

Warnings and precautions

Take special care with VIDAMACE 50 mg:

- if you have liver disease
- if you suffer from heart failure

- if you have or have had a disease of the pancreas
- if you are taking an antidiabetic medicine known as a sulphonylurea (your doctor may want to reduce your dose of the sulphonylurea when you take it together with VIDAMACE 50 mg in order to avoid low blood glucose [hypoglycaemia])
- if you have type 1 diabetes (i.e. your body does not produce insulin) or if you have a condition called diabetic ketoacidosis, VIDAMACE 50 mg should not be used in these cases
- if you have moderate or severe kidney disease (your doctor may advise you to take a lower dose of VIDAMACE 50 mg)
- if you are on dialysis.

A test to determine your liver function will be performed before the start of VIDAMACE 50 mg 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 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 healthcare provider.
You are also advised to pay particular attention to new onset of blisters or ulcers while taking VIDAMACE 50 mg. Should these occur, you should promptly consult your doctor.

Children and adolescents

The use of VIDAMACE 50 mg in children and adolescents younger than 18 years is not recommended.

Other medicines and VIDAMACE 50 mg

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Your doctor may wish to alter your dose of VIDAMACE 50 mg if you are taking other medicines such as:

- ACE inhibitors, e.g. enalapril, lisonopril (medicines used to treat high blood pressure), as there may be an increased risk of side effects
- thiazides diuretics (also called water tablets), e.g. hydrochlorothiazide, chlorthalidone, as the effect of VIDAMACE 50 mg may be reduced
- corticosteroids (generally used to treat inflammation), e.g. prednisone, as the effect of VIDAMACE 50 mg may be reduced
- thyroid medicines, e.g. thyroxine, as the effect of VIDAMACE 50 mg may be reduced
- certain medicines affecting the nervous system, as the effect of VIDAMACE 50 mg may be reduced.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before using VIDAMACE 50 mg.

The safety of VIDAMACE 50 mg in pregnancy and breastfeeding has not been established.

You should not use VIDAMACE 50 mg if you are pregnant or breastfeeding your baby.

Driving and using machines

VIDAMACE 50 mg may cause dizziness.

It is not always possible to predict to what extent VIDAMACE 50 mg may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which VIDAMACE 50 mg affects you.

VIDAMACE 50 mg contains lactose

VIDAMACE 50 mg contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking VIDAMACE 50 mg.

VIDAMACE 50 mg 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 VIDAMACE 50 mg

Do not share medicines prescribed for you with any other person. Always use VIDAMACE 50 mg exactly as your doctor has instructed. You should check with your doctor or pharmacist if you are unsure.

The amount of VIDAMACE 50 mg patient's have to take varies depending on their condition. Your doctor will tell you exactly how many tablets of VIDAMACE 50 mg to take. The maximum daily dose is 100 mg.

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

Adults:

The usual dose is either:

- 50 mg daily taken as one dose in the morning if you are taking VIDAMACE 50 mg 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 VIDAMACE 50 mg alone, with another medicine called metformin, 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.

Elderly:

If you are 65 years or older, the same dosage as stated above is recommended.

Children:

VIDAMACE 50 mg is not recommended in children and adolescents under the age of 18 years.

Your doctor will tell you how long your treatment with VIDAMACE 50 mg will last. You may have to stay on the 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 you have the impression that the effect of VIDAMACE 50 mg is too strong or too weak, tell your doctor or pharmacist.

If you take more VIDAMACE 50 mg than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Symptoms of overdose may include:

- muscle pain, pins and needles sensation, fever and swelling, pancreas, kidney and liver problems.

If you forget to take VIDAMACE 50 mg

If you forget to take VIDAMACE 50 mg, take as soon as you remember on the same day.
Do not take a double dose to make up for forgotten individual doses.

If you stop taking VIDAMACE 50 mg

Do not stop taking VIDAMACE 50 mg 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

VIDAMACE 50 mg can have side effects.
Not all side effects reported for VIDAMACE 50 mg are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using VIDAMACE 50 mg, please consult your healthcare provider for advice.

If any of the following happens, stop using VIDAMACE 50 mg and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- 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.
- liver disease (hepatitis): symptoms include yellow skin and eyes, nausea, loss of appetite or dark-coloured urine, which may indicate liver disease (hepatitis).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- low blood glucose (symptoms include hunger, dizziness, looking pale, fast heartbeat and shaking)

- trembling, headache, dizziness, chill
- nausea, constipation and gastroesophageal reflux disease, symptoms include heartburn, upper abdominal pain and chest pain
- excessive sweating
- abnormal physical weakness or lack of energy
- swollen hands, ankle or feet (peripheral oedema).

Less frequent side effects:

- diarrhoea and flatulence (symptoms include stomach pain, nausea, vomiting, fever and weight loss).

Frequency unknown side effects:

- itchy rash, localised peeling of skin or blisters
- joint pain
- redness and swelling (inflammation) of the gallbladder (cholecystitis)
- intestinal obstruction.

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 SAHPRA website. An email can be sent directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

5. How to store VIDAMACE 50 mg

Store all medicines out of reach of children.

Store at or below 30 ˚C. Keep blisters in carton until use.

Do not use after the expiry date stated on the carton. 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 VIDAMACE 50 mg contains

Each tablet contains 50 mg vildagliptin.

The other ingredients are:

Microcrystalline cellulose, croscarmellose sodium, lactose, magnesium stearate.

What VIDAMACE 50 mg looks like and contents of the pack

White to light yellowish, round, flat-faced bevelled edge tablets, debossed with “50” on one side with dimensions, diameter: 8,1 ± 0,1 mm and thickness: 3,2 ± 0,3 mm.

VIDAMACE 50 mg tablets are available in OPA/ALU/PVC-Aluminium foil blisters. Pack sizes of 30 or 60 tablets per outer carton. Not all pack sizes will be marketed.

Holder of Certificate of Registration

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