

VILDAMAC 50(VILDAGLIPTIN TABLETS 50MG)

Vildagliptin 50mg

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1. What VILDAMAC 50 is used for

Each VILDAMAC 50 tablet contains 50 mg of the active substance vildagliptin. VILDAMAC 50 is a medicine used to treat 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. Such medicines are known as oral antidiabetics.

Type 2 diabetes develops if the body does not produce enough insulin or if the insulin that your 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 that helps to lower the level of sugar in your blood, especially after meals.

Glucagon is a substance that triggers the production of sugar by the liver, causing the blood sugar level to rise. The pancreas makes both of these substances.

2. How VILDAMAC 50 works

VILDAMAC 50 works by making the pancreas produce more insulin and less glucagon. VILDAMAC 50 helps to control the blood sugar level.

Your doctor will prescribe VILDAMAC 50 either alone or in combination with other antidiabetics depending on your condition.

It is important that you continue to follow the diet and/or exercise recommended to you while you are on treatment with VILDAMAC 50. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

3. Before you use VILDAMAC 50

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 or any of the other ingredients of VILDAMAC 50.

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 VILDAMAC 50 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 VILDAMAC 50.

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 VILDAMAC 50

- If you are pregnant or plan to become pregnant.
- If you are breast-feeding.
- If you have kidney problems.
- If you have liver problems.
- If you are suffering from heart failure, your doctor will decide whether or not to prescribe VILDAMAC 50 depending on the degree of your condition.

VILDAMAC 50 is not a substitute for insulin. You should therefore neither receive VILDAMAC 50 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.

If any of these apply to you, tell your doctor before you take VILDAMAC 50.

Monitoring your VILDAMAC 50 treatment

Your doctor should ensure that the following tests are performed:

- Blood and urine tested for sugar regularly
- Check how your liver functions:
- at start of treatment
- every 3 months during the first year of treatment and regularly thereafter

- if your doctor has told you to stop treatment with VILDAMAC 50 because of liver problems you should never start taking VILDAMAC 50 again.

VILDAMAC 50 and use in older people

VILDAMAC 50 can be used by elderly patients

VILDAMAC 50 in children/adolescents

There is no information available on the use of VILDAMAC 50 in children and adolescents (age below 18 years). The use of VILDAMAC 50 in these patients is therefore not recommended.

Important information about some of the ingredients of VILDAMAC 50

VILDAMAC 50 contains an ingredient called lactose (milk sugar). If you have severe lactose intolerance, galactose intolerance, or glucose- galactose malabsorption, tell your doctor before taking VILDAMAC 50.

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.

4. How to use VILDAMAC 50

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 VILDAMAC 50 than your doctor has prescribed.

How much to use

Your doctor will tell you exactly how many tablets of VILDAMAC 50 to take. The usual dose using VILDAMAC 50 50mg tablets is 50 mg or 100 mg a day. The 50 mg dose should be taken as 50 mg once a day . The 100 mg dose should be taken as 50 mg twice a day . Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose. Your doctor will prescribe VILDAMAC 50 either alone or in combination with other antidiabetics, depending on your condition.

When to use it:

VILDAMAC 50 tablets should be taken in the morning (50mg once a day) or in

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the morning and evening (50mg twice daily).

VILDAMAC 50 can be taken with or without a meal.

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

How long to use it:

Continue taking VILDAMAC 50 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 has told you to stop treatment with VILDAMAC 50 because of liver problems you should never start taking VILDAMAC 50 again.

If you have questions about how long to take VILDAMAC 50, talk to your doctor.

If you forget to use it

If you forget to take VILDAMAC 50, take it as soon as you remember. Then take your next dose at the 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.

5. While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking VILDAMAC 50.

Tell your doctor immediately if you become pregnant while taking this medication.

- 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 VILDAMAC 50 to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of:

Driving and using machines

Patients experiencing dizziness should avoid driving vehicles or using machines.

6. SIDE EFFECTS

VILDAMAC 50 can have some side effects in some people. Some patients have experienced the following side effects while taking VILDAMAC 50 or in combination with another antidiabetic medication:

Some symptoms need immediate medical attention

You should stop taking VILDAMAC 50 and see your doctor immediately if you experience the following symptoms:

- 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/or eyes, nausea, loss of appetite, dark-colored urine (possible symptoms of liver problems).
- Severe upper stomach pain (possible symptom of inflamed pancreas).
- Headache, drowsiness, weakness, dizziness, confusion, irritability, hunger, fast heartbeat, sweating, feeling jittery (possible symptoms of low level of sugar in the blood known as 'hypoglycemia')

Other side effects

Common side effects (likely to occur in more than 1 in 10 patients)

Uncommon side effects (likely to occur in fewer than 1 in 100 patients).

Some patients have had the following side effects while taking VILDAMAC 50 alone:

- Common: Dizziness.
- Uncommon: Headache, constipation, swollen hands, ankles or feet (edema).

Some patients have had the following side effects while taking VILDAMAC 50 and metformin:

- Common: Trembling, headache, dizziness.

Some patients have had the following side effects while taking VILDAMAC 50 and a sulphonylurea:

- Common: Trembling, headache, dizziness, weakness

Some patients have had the following side effects while taking VILDAMAC 50 and a glitazone:

- Common: Weight increase, swollen hands, ankles or feet (edema).
- Uncommon: Headache.

Some patients have had the following side effects while taking VILDAMAC 50 and insulin (with or without metformin):

- Common: Headache, chills, nausea, decreased blood sugar, heartburn.
- Uncommon: Diarrhea, flatulence.

Some patients have had the following side effects while taking VILDAMAC 50 with metformin and a sulphonylurea:

- Common: Dizziness, trembling, weakness, excessive sweating,

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

Some patients have experienced other side effects while taking VILDAMAC 50 alone or in combination with another antidiabetic medication:

- Itchy rash, areas of peeling skin or blisters, joint pain.

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

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

You may report any side effects of adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my (Consumer → Reporting → Reporting Side Effects to Medicine (ConSERF) or Vaccines (AEFI)).

7. Storage and disposal of VILDAMAC 50

- Storage

- Store below 30°C. Protect from moisture.
Store in the original package
- 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

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blister or carton after 'EXP'. The expiry date refers to the last day of that month.

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

8. PRODUCT DESCRIPTION

- What it looks like

White to off white, round, flat faced beveled edge, uncoated tablets debossed with 'L45' on one side and plain on other side (Approximate size: 8 mm).

VILDAMAC 50 comes in Alu (OPA/ALU/PVC) / Alu blister packs Available in pack size of 3 x 10's

- What VILDAMAC 50 contains

- Active ingredient:

Vildagliptin

- Inactive ingredients:

Lactose , Microcrystalline Cellulose,
Sodium Starch Glycolate
Type A and Magnesium stearate

- MAL Number:

MALXXXXXXX

9. Manufacturer and Product Registration Holder

Manufacturer:

MACLEODS PHARMACEUTICALS LTD.

Block N2,Village Theda, Post Office
Lodhimajra,Tehsil Baddi, District Solan,
Himachal Pradesh-174101, India.

Product Registration Holder:

Macleods Pharmaceutical Sdn. Bhd.,
A2-27-1 Soho Suites KLCC, Jalan Perak,
50450 Kuala Lumpur, Malaysia.

10. Date of revision

11/08/2026

11. Serial Number

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