

Vilget™

[Vildagliptin Tablets]

50mg Tablets

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

WHAT IS IN THIS LEAFLET

1. What VILGET is and what it is used for
2. Before you use VILGET
3. How to use VILGET
4. Possible Side Effects
5. How to Store VILGET
6. Further Information
7. Date of Preparation
8. Manufacturer and Product Registration Holder

WHAT VILGET IS AND WHAT IT IS USED FOR

Vilget contains the active substance vildagliptin, belongs to a group of medicines called "oral antidiabetics".

Vilget 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 Vilget 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.

Vilget 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.

BEFORE YOU USE VILGET

Do not take or use VILGET

If you are allergic to vildagliptin or any of the other ingredients of Vilget, do not take this medicine and talk to your doctor.

Take special care with Vilget

Talk to your doctor, pharmacist or diabetes nurse before taking Vilget:

- 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 Vilget 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 Vilget).
- 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 Vilget.

A test to determine your liver function will be performed before the start of Vilget 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 Vilget in children and adolescents up to 18 years of age is not recommended.

Other medicines and vilget

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

Driving and using machines

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

Vilget contains lactose

Vilget 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.

HOW TO USE VILGET

How to use Vilget

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Swallow the tablets whole with some water.

How often Vilget should be used

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

The usual dose of Vilget is either:

- 50 mg daily taken as one dose in the morning if you are taking Vilget 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 Vilget 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 Vilget

Swallow the tablets whole with water

How long Vilget should be used for

- Take Vilget 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 Vilget than you should

If you take too many Vilget 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 Vilget

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 Vilget

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

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 Vilget and see your doctor immediately if you experience the following side effects:

- Angioedema (rare): 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 Vilget and metformin:

Common: Trembling, headache, dizziness, nausea, low blood glucose.

Uncommon: Tiredness.

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

Common: Trembling, headache, dizziness, weakness, low blood glucose.

Uncommon: Constipation.

Very rare: Sore throat, runny nose.

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

Common: Weight increase, swollen hands, ankle or feet (edema).

Uncommon: Headache, weakness, low blood glucose.

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

Common: Dizziness.

Uncommon: Headache, constipation, swollen hands, ankle or feet (edema), joint pain, low blood glucose.

Very rare: Sore throat, runny nose, fever.

Some patients have had the following side effects while taking Vilget, metformin and a sulphonyl urea:

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

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

Common: Headache, chills, nausea (feeling sick), low blood glucose, heartburn.

Uncommon: Diarrhea, flatulence.

HOW TO STORE VILGET

Storage:

- Do not store above 30°C.
- Protect from sunlight & moisture.
- Keep out of reach and sight of children.

How to check the expiry date of medicine

Do not use Vilget after the expiry date which is stated on the carton and the blister pack after the word "EXP".

The expiry date refers to the last day of that month.

Disposal

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.

FURTHER INFORMATION

Product Description:

What Vilget tablets looks like:

Vilget Tablets 50mg are white colored, round shaped tablet, plain on both sides.

Ingredient:

Active ingredient:

Vildagliptin

In-active Ingredients:

Microcrystalline Cellulose (Avicel PH-102 DC Grade), Lactose Anhydrous, Sodium Starch Glycolate and Magnesium Stearate.

DATE OF PREPARATION

January 17, 2017



MANUFACTURER AND PRODUCT REGISTRATION HOLDER:

Getz Pharma (Pvt.) Ltd. 29-30/27, Korangi Industrial Area,
Karachi - 74900, Pakistan.

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