



[Vildagliptin+Metformin HCl Tablets]

50mg+850mg 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

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WHAT VILGET-M IS AND WHAT IT IS USED FOR

VILGET-M tablets contains the active substances, vildagliptin and metformin, which belong to a group of medicines called "oral antidiabetics". VILGET-M is used to treat adult patients with type 2 diabetes. This type of diabetes is also known as non-insulin-dependent diabetes mellitus. Both active substances, vildagliptin and metformin, help to control the level of sugar in the blood. The substance vildagliptin works by making the pancreas produce more insulin and less glucagon. The substance metformin works by helping the body to make better use of insulin. This medicine has been shown to reduce blood sugar, which may help to prevent complications from your diabetes.

BEFORE YOU USE VILGET-M

Do not take or use VILGET-M

- If you are allergic (hypersensitive) to vildagliptin, metformin or any other ingredients included in VILGET-M tablets. If you think you may be allergic to any of these, talk to your doctor before taking VILGET-M.
- If you have uncontrolled diabetes, with, for example, severe hyperglycemia (high blood glucose), nausea, vomiting, diarrhea, rapid weight loss, lactic acidosis or ketoacidosis. Ketoacidosis is a condition in which substances called ketone bodies accumulate in the blood and which can lead to diabetic pre-coma. Symptoms include stomach pain, fast and deep breathing, sleepiness or your breath developing an unusual fruity smell.
- If you have recently had a heart attack or if you have heart failure or serious problems with your blood circulation or difficulties in breathing which could be a sign of heart problems.
- If you have severely reduced kidney function.
- If you have a severe infection or are seriously dehydrated.
- If you are going to have a contrast x-ray (a specific type of x-ray involving an injectable dye).
- If you have liver problems.
- If you drink alcohol excessively (whether every day or only from time to time).
- If you are breast-feeding.

Take special care with VILGET-M

Risk of lactic acidosis

- VILGET-M may cause a very rare, but very serious side effect called lactic acidosis, particularly if your kidneys are not working properly. The risk of developing lactic acidosis is also increased with uncontrolled diabetes, serious infections, prolonged fasting or alcohol intake, dehydration, liver problems and any medical conditions in which a part of the body has a reduced supply of oxygen (such as acute severe heart disease). If any of the above apply to you, talk to your doctor for further instructions.
- Stop taking VILGET-M for a short time if you have a condition that may be associated with dehydration (significant loss of body fluids) such as severe vomiting, diarrhea, fever, exposure to heat or if you drink less fluid than normal. Talk to your doctor for further instructions.
- Stop taking VILGET-M and contact a doctor or the nearest hospital immediately if you experience some of the symptoms of lactic acidosis, as this condition may lead to coma.

Symptoms of lactic acidosis include:

- Vomiting.
- Stomach ache (abdominal pain).
- Muscle cramps.
- A general feeling of not being well with severe tiredness.
- Difficulty in breathing.
- Reduced body temperature and heartbeat.
- Lactic acidosis is a medical emergency and must be treated in a hospital.

VILGET-M is not a substitute for insulin. Therefore, you should not receive VILGET-M for the treatment of type 1 diabetes.

Talk to your doctor, pharmacist or diabetes nurse before taking VILGET-M if you have or have had a disease of the pancreas.

Talk to your doctor, pharmacist or diabetes nurse before taking VILGET-M if you are taking an anti-diabetic medicine known as a sulphonyl urea. Your doctor may want to reduce your dose of the sulphonyl urea when you take it together with VILGET-M in order to avoid low blood glucose (hypoglycemia).

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-M. Should these occur, you should promptly consult your doctor.

If you need to have major surgery you must stop taking VILGET-M during and for some time after the procedure. Your doctor will decide when you must stop and when to restart your treatment with VILGET-M.

A test to determine your liver function will be performed before the start of VILGET-M treatment, at three months intervals for the first year and periodically thereafter. This is so that signs of increased liver enzymes can be detected as early as possible. During treatment with VILGET-M, your doctor will check your kidney function at least once a year or more frequently if you are elderly and/or have worsening renal function. Your doctor will test your blood and urine for sugar regularly.

Children and adolescents

The use of VILGET-M in children and adolescents up to 18 years of age is not recommended.

Other medicines & Vilget-M

If you need to have an injection of a contrast medium that contains iodine into your bloodstream, for example in the context of an X-ray or scan, you must stop taking VILGET-M before or at the time of the injection. Your doctor will decide when you must stop and when to restart your treatment with VILGET-M.

Tell your doctor if you are taking, have recently taken or might take any other medicines. You may need more frequent blood glucose and kidney function tests, or your doctor may need to adjust the dosage of VILGET-M. It is especially important to mention the following:

- Glucocorticoids generally used to treat inflammation.
- Beta-2 agonists generally used to treat respiratory disorders.
- Other medicines used to treat diabetes.
- Medicines which increase urine production (diuretics).
- Medicines used to treat pain and inflammation (NSAID and COX-2-inhibitors, such as ibuprofen and celecoxib).
- Certain medicines for the treatment of high blood pressure (ACE inhibitors and angiotensin II receptor antagonists).
- Certain medicines affecting the thyroid, or
- Certain medicines affecting the nervous system.

VILGET-M with Alcohol

Avoid excessive alcohol intake while taking VILGET-M since this may increase the risk of lactic acidosis.

Pregnancy and breast-feeding

- 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 VILGET-M during pregnancy.
- Do not use VILGET-M if you are pregnant or breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

If you feel dizzy while taking VILGET-M, do not drive or use any tools or machines.

HOW TO USE VILGET-M

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 a glass of water
- Take one tablet in the morning and the other in the evening with or just after food. Taking the tablet just after food will lower the risk of an upset stomach.

Continue to follow any advice about diet that your doctor has given you. In particular, if you are following a diabetic weight control diet, continue with this while you are taking VILGET-M.

How often VILGET-M should be used

The recommended dose is one film-coated tablet of either 50 mg/850 mg taken twice a day. If you have reduced kidney function, your doctor may prescribe a lower dose. Also if you are taking an anti-diabetic medicine known as a sulphonyl urea your doctor may prescribe a lower dose.

Your doctor may prescribe this medicine alone or with certain other medicines that lower the level of sugar in your blood.

How long VILGET-M should be used for

The amount of VILGET-M that people have to take varies depending on their condition. Your doctor will tell you exactly the dose of VILGET-M to take.

If you take more VILGET-M than you should

If you take too many VILGET-M tablets, or if someone else takes your tablets, talk to a doctor or pharmacist immediately. Medical attention may be necessary. If you have to go to a doctor or hospital, take the pack and this leaflet with you.

If you forget to take VILGET-M

If you forget to take a tablet, take it with your next meal unless you are due to take one then anyway. Do not take a double dose (two tablets at once) to make up for a forgotten tablet.

If you stop taking VILGET-M

Continue to take this medicine as long as your doctor prescribes it so that it can continue to control your blood sugar. Do not stop taking VILGET-M unless your doctor tells you to. If you have any questions about how long to take this medicine, talk to your doctor.

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

POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

You should stop taking VILGET-M and see your doctor immediately if you experience the following side effects:

- Lactic acidosis: VILGET-M may cause a very rare, but very serious side effect called lactic acidosis. If this happens you must stop taking VILGET-M and contact a doctor or the nearest hospital immediately, as lactic acidosis may lead to coma.
- Angioedema: Symptoms include swollen face, tongue or throat, difficulty swallowing, difficulty breathing, sudden onset of 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-colored 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.

Other side effects

Some patients have experienced the following side effects while taking VILGET-M:

- *Very common:* nausea, vomiting, diarrhea, pain in and around the stomach (abdominal pain), loss of appetite.
- *Common:* dizziness, headache, trembling that cannot be controlled, metallic taste, low blood glucose.
- *Uncommon:* joint pain, tiredness, constipation, swollen hands, ankle or feet (edema).
- *Very rare:* sore throat, runny nose, fever; signs of a high level of lactic acid in the blood (known as lactic acidosis) such as drowsiness or dizziness, severe nausea or vomiting, abdominal pain, irregular heart beat or deep, rapid breathing; redness of the skin, itching; decreased vitamin B12 levels (paleness, tiredness, mental symptoms such as confusion or memory disturbances).

Some patients have experienced the following side effects while taking VILGET-M and a sulphonylurea:

- *Common:* dizziness, tremor, weakness, low blood glucose, excessive sweating.

Some patients have had the following side effects while taking VILGET-M and insulin:

- *Common:* headache, chills, nausea (feeling sick), low blood glucose, heartburn.
- *Uncommon:* diarrhea, flatulence.

Since this product has 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, localized peeling of skin or blisters, muscle pain.

HOW TO STORE VILGET-M

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-M 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-M looks like:

Light pink colored, oblong shaped, film-coated tablet, engraved "GETZ" on one side and bisect line on the other side.

Ingredient:

Active ingredient:

Vildagliptin
Metformin HCl

In-active Ingredients:

Microcrystalline Cellulose (Avicel PH-101), Hydroxypropyl Cellulose (Klucel LF PHARM), Croscarmellose Sodium, Magnesium Stearate, Opadry AMB White 80W68912, & Ferric Oxide Red.

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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