

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory

# VILDUS MET

## Vildagliptin 50 mg and Metformin HCL 1000 mg Tablets

### Composition :

Each film coated tablet contains

Vildagliptin	50mg
Metformin HCl BP	1000mg

Colours: Ferric oxide red USP NF, Ferric oxide yellow USP NF, Titanium Dioxide BP

### INDICATIONS:

The active substances of **VILDUS MET**, vildagliptin and metformin, belong to a group of medicines called "oral antidiabetics".

**VILDUS MET** is used to treat adult patients with type 2 diabetes. This type of diabetes is also known as noninsulin-dependent diabetes mellitus.

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 if the body produces too much glucagon. Both insulin and glucagon are made in the pancreas. Insulin helps to lower the level of sugar in the blood, especially after meals. Glucagon triggers the liver to make sugar, causing the blood sugar level to rise.

### How VILDUS MET works

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.

### CONTRAINDICATIONS:

Do not take **VILDUS MET**

- if you are allergic to vildagliptin, metformin. If you think you may be allergic to any of these, talk to your doctor before taking **VILDUS MET**.
- if you have uncontrolled diabetes, with, for example, severe hyperglycaemia (high blood glucose), nausea, vomiting, diarrhoea, rapid weight loss, lactic acidosis (see "Risk of lactic acidosis" below) 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 (have lost a lot of water from your body).
- if you are going to have a contrast x-ray (a specific type of x-ray involving an injectable dye). Please also see information about this in section "Warnings and precautions".
- if you have liver problems.
- if you drink alcohol excessively (whether every day or only from time to time).

### PRECAUTIONS:

#### *Risk of lactic acidosis*

**VILDUS MET** 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 (see further information below), 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 **VILDUS MET** for a short time if you have a condition that may be associated with dehydration (significant loss of body fluids) such as severe vomiting, diarrhoea, fever, exposure to heat or if you drink less fluid than normal. Talk to your doctor for further instructions.

Stop taking **VILDUS MET** 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.

**VILDUS MET** is not a substitute for insulin. Therefore, you should not receive **VILDUS MET** for the treatment of type 1 diabetes.

Talk to your doctor, pharmacist or nurse before taking **VILDUS MET** if you have or have had a disease of the pancreas.

Talk to your doctor, pharmacist or nurse before taking **VILDUS MET** 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

**VILDUS MET**. 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 **VILDUS MET**. Should these occur, you should promptly consult your doctor.

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

A test to determine your liver function will be performed before the start of **VILDUS MET** 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.

During treatment with **VILDUS MET**, 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 **VILDUS MET** in children and adolescents up to 18 years of age is not recommended.

**USE IN PREGNANCY:**

- If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Your doctor will discuss with you the potential risk of taking **VILDUS MET** during pregnancy.
  - Do not use **VILDUS MET** if you are pregnant or breast-feeding (see also "Do not take **VILDUS MET**").
- Ask your doctor or pharmacist for advice before taking any medicine.

**DRUG INTERACTIONS:**

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 **VILDUS MET** before or at the time of the injection. Your doctor will decide when you must stop and when to restart your treatment with **VILDUS MET**.

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 **VILDUS MET**. 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.

**VILDUS MET with alcohol**

Avoid excessive alcohol intake while taking **VILDUS MET** since this may increase the risk of lactic acidosis.

**ADVERSE REACTIONS:**

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

You should stop taking **VILDUS MET** and see your doctor immediately if you experience the following side effects:

- Lactic acidosis (very rare: may affect up to 1 user in 10,000): **VILDUS MET** may cause a very rare, but very serious side effect called lactic acidosis (see section "Warnings and precautions"). If this happens you must stop taking **VILDUS MET** and contact a doctor or the nearest hospital immediately, as lactic acidosis may lead to coma.
- Angioedema (rare: may affect up to 1 in 1,000 people): 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) (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 experienced the following side effects while taking **VILDUS MET**:

- Very common (may affect more than 1 in 10 people): nausea, vomiting, diarrhoea, pain in and around the stomach (abdominal pain), loss of appetite.

- Common (may affect up to 1 in 10 people): dizziness, headache, trembling that cannot be controlled, metallic taste, low blood glucose.- Uncommon (may affect up to 1 in 100 people): joint pain, tiredness, constipation, swollen hands, ankle or feet.

Some patients have experienced the following side effects while taking **VILDUS MET** and a sulphonylurea:

- Common: dizziness, tremor, weakness, low blood glucose, excessive sweating. Some patients have had the following side effects while taking **VILDUS MET** and insulin:
- Common: headache, chills, nausea (feeling sick), low blood glucose, heartburn.
- Uncommon: diarrhoea, 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, localised peeling of skin or blisters, muscle pain.

**OVERDOSAGE:**

If you take too many **VILDUS MET** 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.

**DOSAGE & ADMINISTRATION:**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one film-coated tablet of either 50 mg/850 mg or 50 mg/1000 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 sulphonylurea 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.

**STORAGE CONDITIONS:**

Store below 30°C. Protect from light and moisture.

**Keep the medicine out of reach of children.**

**PRESENTATION:**

60 Tablets.

Marketed by:



**PYXUS PHARMACEUTICALS PVT. LTD.**

A/707, Mondeal Heights, Beside Novotel Hotel,  
Nr. Iscon Square, S.G. Highway, Ahmedabad,  
Gujarat- 380015 (India).