PATIENT INFORMATION LEAFLET SCHEDULING STATUS

S3

VILDAMET 50/ 850 mg

VILDAMET 50/ 1000 mg

Vildagliptin 50 mg / Metformin HCL 850 mg or

Vildagliptin 50 mg/Metformin HCL 1000 mg

Sugar free

Read all of this leaflet carefully before you start taking VILDAMET

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **VILDAMET** 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

1. What **VILDAMET i**s and what it is used for

2. What you need to know before you take **VILDAMET**

3. How to take **VILDAMET**

4. Possible side effects

5. How to store **VILDAMET**

6. Contents of the pack and other information

1. What VILDAMET is and what is it used for:

VILDAMET is available as tablets. Each tablet of **VILDAMET** contains two active substances: vildagliptin and metformin hydrochloride.

VILDAMET is a medicine used to treat type 2 diabetes.

VILDAMET helps to control the level of sugar in the blood. Such medicines are known as oral antidiabetics.

Your doctor has prescribed **VILDAMET** for you if your blood sugar level has been controlled when you take vildagliptin and metformin hydrochloride as separate tablets and at the same dosages.

VILDAMET can also be prescribed for you in combination with a sulphonylurea if your blood sugar level has been controlled on vildagliptin, metformin hydrochloride and a sulphonylurea as separate tablets and the same dosages.

VILDAMET can also be prescribed for you as add-on to insulin if your blood sugar levels has been controlled on a stable dose of insulin plus vildagliptin and metformin hydrochloride as separate tablets and the same dosages.

It is important that you continue to follow the diet and/or exercise advised for you whilst you are on treatment with **VILDAMET**.

Ask your doctor if you have any questions about why **VILDAMET** has been prescribed for you.

2. What you need to know before you take VILDAMET

Do not take VILDAMET:

• if you are allergic (hypersensitive) to vildagliptin, metformin hydrochloride or any of the other ingredients of **VILDAMET** (listed in section 6).

• if you have severely reduced kidney function (this will be decided by your doctor),

• if you have recently had a heart attack, have a heart failure, or if you have serious problems with your blood circulation, including shock or breathing difficulties,

• if you have or have had serious complications of your diabetes, such as diabetic ketoacidosis (a complication of diabetes involving rapid weight loss, nausea or vomiting) or diabetic coma,

• if you have a problem with your liver,

• if you drink alcohol excessively (whether every day or only from time to time).

Warnings and precautions

Take special care with **VILDAMET**:

- **VILDAMET** is not a substitute for insulin. You should therefore neither receive **VILDAMET** 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 you experience one or more of the following symptoms: feeling cold and uncomfortable, muscle pain, drowsiness, severe nausea or vomiting, abdominal pain, dizziness, irregular heartbeat, or rapid breathing. Patients taking metformin (one of the active substances of **VILDAMET**) have experienced a condition called lactic acidosis (too much lactic acid in the blood). This is more likely to occur in patients whose kidneys are not working properly.
- If you experience nausea, sweating, weakness, dizziness, trembling, headache (signs of low level of sugar (glucose) in the blood) which could be due to lack of food, too strenuous exercise without sufficient food intake, excessive alcohol intake (usually not with **VILDAMET** alone).
- If you are going to have a contrast X-ray (a specific type of X-ray involving an injectable dye). You will need to temporarily stop taking **VILDAMET** before or at the time of and for a few days after the procedure.
- If you are scheduled for a surgical procedure, **VILDAMET** should be suspended.

If you experience some of these symptoms, stop taking **VILDAMET** and consult a doctor immediately:

- If you are going to have an operation under general anaesthetic, you may need to stop taking **VILDAMET** for a couple of days before and after the procedure. Your

doctor will decide when you must stop and when to restart your treatment with **VILDAMET**.

• If you drink alcohol excessively, either every day or only from time to time.

• If you have a liver disease.

• If you have disease of the pancreas

• If your diabetes control worsens suddenly or if you have abnormal blood sugar tests or feel ill, contact your doctor.

• If you experience joint pain, sometimes severe.

If any of these apply to you, tell your doctor.

Monitoring your **VILDAMET** treatment:

Your doctor should ensure the following:

• your blood and urine should be tested for sugar regularly

• your kidney function should be checked:

- at start of treatment
- at least once a year whilst you are on treatment
- more often if you are elderly or if your kidney function starts to decrease

• your liver function should be checked:

- at start of treatment

- every 3 months during the first year of treatment and regularly thereafter

• if your doctor told you to stop your treatment with **VILDAMET** because of liver problems, you should never start taking **VILDAMET** again.
• a general blood test at least once a year
• a check of vitamin B12 levels at least every two to three years

VILDAMET and older people:
Your doctor will check how well your kidneys work. You may need more frequent checks if you have kidney problems.

Children and Adolescents
There is no information available on the use of **VILDAMET** in children (age less than 18 years). The use of **VILDAMET** in these patients is therefore not recommended.

Other medicines and VILDAMET
Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional 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. This is particularly important with the following medicines:
• certain medicines used to treat infections (e.g. vancomycin, trimethoprim)
• certain medicines used to treat inflammation (e.g. corticosteroids)

• certain medicines used to treat high blood pressure (e.g. amiloride, triamterene, nifedipine, enalapril, losartan, diuretics)

• certain medicines used to treat irregular heartbeat (e.g. digoxin, quinidine)

• certain medicines used to reduce pain (e.g. morphine, diclofenac)

• certain medicines used to treat stomach disorders (e.g. cimetidine, ranitidine)

• certain medicines used to treat some psychiatric disorders (e.g. phenothiazine)

• certain medicines used to treat thyroid disorders

• oral contraceptives, certain medicines used to reduce symptoms in women experiencing menopause or osteoporosis (e.g. oestrogen)

Do not drink alcohol excessively or take medicines that contain alcohol whilst taking **VILDAMET** tablets.

Taking VILDAMET with food and drink

It is recommended that you take your tablets either with or just after food. This will reduce the chance of you getting an upset stomach.

Pregnancy breastfeeding and fertility

Safety in pregnancy ,breastfeeding and fertility has not been established.

You should not use **VILDAMET** if you are pregnant or breastfeeding your infant.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Your doctor will discuss with you the potential risk of taking **VILDAMET** during pregnancy.

Driving and using machines

If you feel dizzy while taking **VILDAMET**, do not drive vehicles or use any tools or machines until you are well enough to do so again.

3. How to take VILDAMET

Follow all instructions given to you by your doctor and pharmacist carefully.
You should check with your doctor or pharmacist if you are unsure.
If you get the impression that the effect of **VILDAMET** is too strong or too weak, tell your doctor or pharmacist.

How much VILDAMET to take

Your doctor will tell you exactly how many tablets of **VILDAMET** to take. Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.
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.
Do not take more **VILDAMET** than your doctor has prescribed.

When and how to take VILDAMET

VILDAMET should be taken in the morning and/or in the evening. It is recommended that you take your tablets either with or just after food. This will reduce the chance of you getting an upset stomach.
The tablets should be swallowed whole with a glass of water.

How long to take VILDAMET

Continue taking **VILDAMET** 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 tells you to stop your treatment with **VILDAMET** because of liver problems, you should never start taking **VILDAMET** again.
If you have questions about how long to take **VILDAMET**, talk to your doctor.

If you take more VILDAMET than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.
If you experience severe dizziness, irregular heartbeat, or rapid breathing from low blood sugar, haemodialysis is required to be administered by a healthcare professional with the appropriate supportive treatment that should be initiated according to the patient's clinical signs and symptoms.

If you forget to take VILDAMET

It is advisable to take your medicine at the same time each day. If you forget to take **VILDAMET**, take it as soon as you remember and take your next dose at its 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.

4. Possible side effects

VILDAMET can have side effects.
Not all side effects reported for **VILDAMET** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this

medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **VILDAMET** and tell your doctor immediately or go to the casualty department at your nearest hospital:

• Swollen face, tongue or throat, difficulty swallowing, difficulty breathing, sudden onset of rash or hives (symptoms of severe allergic reaction called 'angioedema').

These are all very serious side effects. If you have them, you have had a serious allergic reaction to **VILDAMET**. 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:

• Feeling cold and uncomfortable, muscle pain, drowsiness, severe nausea or vomiting, abdominal pain, unexplained weight loss, dizziness, irregular heartbeat, or rapid breathing (symptoms of lactic acidosis). If this happens you must stop taking **VILDAMET** and contact a doctor or the nearest hospital immediately, as lactic acidosis may lead to coma.

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

Tell your doctor if you notice any of the following:

Some patients have the following side effects while taking **VILDAMET**:

Frequent Side Effects:

- Swelling of the throat and nasal passages
- Feeling of dizziness , headaches or involuntary trembling

• Nausea, vomiting, diarrhoea, reflux, flatulence, constipation or pain in the abdomen.

• Excessive sweating, itchiness, rash, skin reddening or peeling of skin

• Pain in the muscle or fatigue

- Lactic acidosis (symptoms mentioned above)

Less Frequent Side Effects:

- Low blood sugar, loss of appetite, decrease in the level of vitamin B12 in the blood (anaemia)
- Metallic taste in mouth
- Inflammation or disease of pancreas
- Inflammation or disease of liver
- Pain in joints or muscle
- Fatigue, chills, swollen hands, ankle or feet (oedema)
- Abnormal liver function test results

Side Effects Frequency Unknown:

- Localised peeling of skin or blisters.

If you notice any other 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 "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **VILDAMET**.

5. How to store VILDAMET

• Store at or below 30°C in the original package.

• Protect from moisture. Do not remove from original packaging until required for use.

• Do not use after the expiry date shown on the box.

• Do not use any **VILDAMET** pack that is damaged or shows signs of tampering.

• Keep out of the reach of children.

6. Content of the pack and other information

Each **VILDAMET** 50 / 850 mg tablet contains 50 mg vildagliptin and 850 mg metformin hydrochloride.

Each **VILDAMET** 50 / 1000 mg tablet contains 50 mg vildagliptin and 1 000 mg metformin hydrochloride.

The other ingredients are:

Ethanol,Hydroxypropyl cellulose, Microcrystalline cellulose (PH-101 and PH-102), magnesium stearate, Opadry AMB II Yellow (colourant) and Povidone K90.

Opadry AMB II Yellow ingredients: Glycerol of FA, Iron Oxide yellow, Polyvinyl alcohol (hydrolyzed), sodium lauryl sulfate, talc and titanium dioxide

What VILDAMET looks like and contents of the pack

VILDAMET 50 mg/ 850 mg film-coated tablets:

Yellow coloured ovaloid shaped tablets plain on both sides.

VILDAMET 50 mg/ 1000 mg film-coated tablets: Dark yellow coloured ovaloid shaped tablets plain on both sides.

VILDAMET film-coated Tablets is available in a Alu-Alu blister pack of 10 tablets that is packed in a printed carton size 3 x 10 along with the package leaflet inside the printed carton.

Holder of Certificate of Registration

Innovata Pharmaceuticals

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South Africa

This leaflet was revised in

New

Registration number

VILDAMET 50/850: 59/21.2/0253

VILDAMET 50/1000: 59/21.2/0254

Access to the corresponding Professional information.

Follow the link for the corresponding Professional Information for **VILDAMET**:

pi-pil-repository.innovata.co.za, alternatively please scan the QR code below:

