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

Crownwood Office Park

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2092

South Africa

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New

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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:

VOORGESTELDE PASIËNT INLIGTINGBILJET

SKEDULERINGSTATUS

S3

VILDAMET 50/ 850 mg

VILDAMET 50/ 1000 mg

Vildagliptien 50 mg / Metformien HCL 850 mg of

Vildagliptien 50 mg/Metformien HCL 1000 mg

Suikervry

Lees die volledige biljet noukeurig deur voordat u VILDAMET begin neem

- Hou hierdie biljet. U mag dit moontlik weer wil lees.
- Indien u verdere vrae het, raadpleeg asseblief u dokter, apteker, verpleegkundige of ander gesondheidsorgvoorsiener.
- **VILDAMET** is vir u persoonlik voorgeskryf en u moet nie u medisyne met ander persone deel nie. Dit kan hulle kwaad aandoen, selfs indien hulle simptome dieselfde is as diè wat u het.

Wat is in hierdie biljet

1. Wat **VILDAMET** is en waarvoor dit gebruik word

2. Wat u behoort te weet voordat u **VILDAMET** neem

3. Hoe om **VILDAMET** te neem

4. Moontlike newe-effekte

5. Hoe om **VILDAMET** te bêre

6. Inhoud van die pakkie en ander inligting

1. Wat VILDAMET is en waarvoor dit gebruik word:

VILDAMET is beskikbaar as tablette. Elke tablet van **VILDAMET** bevat twee aktiewe bestanddele: vildagliptien en metformienhidrochloried.

VILDAMET is ‘n medisyne wat gebruik word vir die behandeling van tipe 2 diabetes.

VILDAMET help met kontrole van die vlak van suiker in die bloed. Sulke medisynes is bekend as orale antidiabetiese medisynes.

U dokter het **VILDAMET** vir u voorgeskryf omdat u bloedsuikervlak gekontrolleer was wanneer u vildagliptien en metformienhidrochloried geneem het as aparte tablette en teen dieselfde doserings.

VILDAMET kan ook vir u voorgeskryf word in kombinasie met 'n sulfonielureum indien u bloedsuikervlakke gekontrolleer was op vildagliptien, metformienhidrochloried en 'n sulfonielureum as aparte tablette en dieselfde doserings.

VILDAMET kan ook voorgeskryf word vir u as aanvulling tot insulien indien u bloedsuikervlakke gekontrolleer was op 'n stabiele dosis van insulien plus vildagliptien en metformienhidrochloried as aparte tablette en dieselfde doserings.

Dit is belangrik dat u voortgaan om u dieet en/of oefening te volg wat aanbeveel word vir u, terwyl u op behandeling is met **VILDAMET**.

Raadpleeg u dokter indien u enige vrae het waarom **VILDAMET** vir u voorgeskryf is.

2. Wat u behoort te weet voordat u VILDAMET neem

Moenie VILDAMET neem:

• indien u allergies (hipersensitief) is vir vildagliptien, metformienhidrochloried of enige van die ander bestanddele van **VILDAMET** nie (aangedui in afdeling 6),

• indien u ernstige afname in nierfunksie het (dit sal besluit word deur u dokter),

• indien u onlangs 'n hartaanval gehad het, hartversaking, of indien u ernstige probleme het met u bloedsirkulasie, insluitend skok of asemhalingsprobleme,

• indien u ernstige komplikasies het of gehad het met u diabetes, soos diabetiese keto-asidose ('n komplikasie van diabetes met betrokkenheid tot vinnige gewigsverlies) of diabetiese koma,

• indien u probleme het met u lewer,

• indien u uitermatig alkohol drink (òf dit elke dag is, òf slegs van tyd tot tyd).

Waarskuwings en voorsorgmaatreëls

Neem spesiale sorg met **VILDAMET**:

• **VILDAMET** is nie ‘n substituut vir insulien nie. U moet nie **VILDAMET** neem vir die behandeling van tipe 1 diabetes nie (d.w.s. u liggaam produseer glad nie insulien nie) of vir die behandeling van ‘n toestand wat genoem word diabetiese keto-asidose nie.

• Indien u een of meer van die volgende simptome ondervind: gevoel van koue en ongemak, spierpyn, lomerigheid, erge naarheid of braking, abdominale pyn, duiseligheid, ongereëlde hartklop, of vinnige asemhaling. Pasiënte wat metformien neem (een van die aktiewe bestanddele van **VILDAMET**) het ‘n toestand ondervind wat genoem word laktiese asidose (te veel laktiese suur in die bloed). Dit sal waarskynlik meer voorkom by pasiënte wie se niere nie behoorlik werk nie.

• Indien u naarheid, sweet, swakheid, duiseligheid, bewerigheid, hoofpyn ondervind (tekens van ‘n lae vlak suiker (glukose) in die bloed) wat kan wees weens gebrek aan voedsel, te uitputtende oefening sonder voldoende voedsel inname, oormatige alkohol inname (gewoonlik nie met **VILDAMET** alleen nie).

• Indien u ‘n kontrasmiddel X-straal moet kry (‘n spesifieke tipe van X-straal met ‘n inspuiting kleurstof). U moet die gebruik van **VILDAMET** moontlik tydelik staak voor of tydens die tydperk daarvan en vir ‘n paar dae na die prosedure.

- Indien u geskeduleer is vir ‘n sjirurgiese prosedure, moet **VILDAMET** gestaak word.

Indien u enige van hierdie simptome ondervind, staak die gebruik van **VILDAMET** en raadpleeg u dokter onmiddellik:

- Indien u ‘n operasie moet ondergaan onder algemene narkose, moet u moontlik die gebruik van **VILDAMET** staak vir ‘n paar dae voor en na die prosedure. U dokter sal besluit wanneer u die behandeling met **VILDAMET** moet staak en wanneer om die behandeling weer te begin.
- Indien u oormatig alkohol drink, of elke dag of slegs van tyd tot tyd.
- Indien u lewersiekte het.
- Indien u siekte van die pankreas het.
- Indien die kontrole van u diabetes skielik agteruitgaan of indien u abnormale bloedsuikertoetse het of ‘n siek gevoel het, kontak u dokter.
- Indien u gewrigspyn ondervind, soms ernstig.

Indien enige van hierdie op u van toepassing is, vertel u dokter.

Monitor u **VILDAMET** behandeling:

U dokter moet seker maak van die volgende:

- u bloed en uriene moet gereëld getoets word vir suiker
- u nierfunksie moet nagegaan word:
    - aan begin van behandeling
    - ten minste jaarliks terwyl u op behandeling is
    - meer dikwels indien u bejaard is of indien u nierfunksie begin afneem

• u lewerfunksie moet nagegaan word:

- aan die begin van behandeling
- elke 3 maande gedurende die eerste jaar van behandeling en gereëld daarna

• indien u dokter u beveel het om behandeling met **VILDAMET** te staak weens lewerprobleme, moet u nie weer begin om **VILDAMET** te neem nie.

• 'n algemene bloedtoets moet ten minste een keer per jaar gedoen word

• 'n nagaan van vitamien B12 vlakke ten minste elke twee tot drie jaar

VILDAMET en ouer persone:

U dokter sal vasstel hoe goed u niere werk. U kan meer dikwels opgevolg word indien u nierprobleme het.

Kinders en Adolessente

Daar is geen inligting beskikbaar omtrent die gebruik van **VILDAMET** in kinders (jonger as 18 jaar) nie. Die gebruik van **VILDAMET** in hierdie pasiënte word dus nie aanbeveel nie.

Ander medisynes en VILDAMET

Vertel altyd u gesondheidsorgvoorsiener indien u enige ander medisyne neem. (Dit sluit in alle komplementêre of tradisionele medisynes.)

Vertel u dokter of apteker indien u enige ander medisynes neem of geneem het.

Onthou ook dié wat nie voorgeskryf is deur u dokter nie. Dit is veral belangrik met die volgende medisynes:

- sekere medisynes vir die behandeling van infeksies (bv. vankomisien, trimetoprim)
- sekere medisynes vir die behandeling van inflammasie (bv. kortikosteroïede)
- sekere medisynes vir die behandeling van hoë bloeddruk (bv. amiloried, triamtereen, nifedipien, enalapril, losartan, diuretiese middels)
- sekere medisynes wat gebruik word vir behandeling van ongereëlde hartklop (bv. digoksien, kinidien)
- sekere medisynes wat gebruik word vir vermindering van pyn (bv. morfien, diklofenak)
- sekere medisynes wat gebruik word vir behandeling van maagsiekte (bv. simetidien, ranitidien)
- sekere medisynes wat gebruik word vir behandeling van sommige psigiatriese afwykings (bv. fenotiasiene)
- sekere medisynes wat gebruik word vir behandeling van tiroïed siektes
- orale kontraseptiewe middels, sekere medisynes wat gebruik word vir vermindering van simptome in vrouens wat menopouse of osteoporose ondervind (bv. estrogene)

Moenie alkohol oormatig drink of medisynes neem wat alkohol bevat terwyl u **VILDAMET** tablette neem nie.

Neem van VILDAMET met voedsel en drankies

Dit word aanbeveel dat u die tablette neem met of net na u voedsel. Dit sal die kans verminder dat u maag omgekrap word.

Swangerskap, borsvoeding en fertiliteit

Veiligheid in swangerskap, borsvoeding en fertiliteit is nog nie vasgestel nie.

U moet nie **VILDAMET** gebruik indien u swanger is of u kleuter borsvoed nie.

Indien u swanger is of borsvoed, dink dat u swanger kan wees of ‘n baba beplan, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgvoorsiener vir advies voordat u hierdie medisyne neem.

U dokter sal die potensiële risiko vir die neem van **VILDAMET** met u bespreek gedurende swangerskap.

Bestuur en gebruik van masjinerie

Indien u duiselig voel terwyl u **VILDAMET** neem, moenie voertuie bestuur of enige gereedskap of masjinerie gebruik nie, totdat u gesond genoeg voel om dit wel te doen.

3. Hoe om VILDAMET te neem

Volg alle instruksies soos aanbeveel deur u dokter en apteker versigtig.

U moet u dokter of apteker raadpleeg indien u nie seker is nie.

Indien u die indruk het dat die effek van **VILDAMET** te sterk of te swak is, raadpleeg u dokter of apteker.

Hoeveel VILDAMET om te neem

U dokter sal u inlig presies hoeveel **VILDAMET** tablette om te neem. Afhangende van hoe u reageer op die behandeling, sal u dokter ‘n hoër of laer dosis voorstel.

Indien u verminderde nierfunksie het, sal u dokter moontlik ‘n laer dosis voorskryf.

Indien u ook ‘n anti-diabetiese medisyne neem wat bekend staan as ‘n sulfonielureum mag u dokter ‘n laer dosis voorskryf.

Moenie meer **VILDAMET** neem as wat u dokter voorgeskryf het nie.

Wanneer en hoe om VILDAMET te neem

VILDAMET moet in die oggend en/of in die aand geneem te word. Dit word aanbeveel dat u die tablette neem òf met òf net na voedsel. Dit sal die kans verminder dat u ‘n omgekrapte maag kry.

Die tablette moet heel ingesluk word met ‘n glas water.

Hoe lank moet u VILDAMET neem

Hou aan met die gebruik van **VILDAMET** elke dag vir so lank as wat u dokter u aanbeveel het. U mag vir ‘n lang tyd op hierdie behandeling bly. U dokter sal u toestand gereëld monitor om na te gaan of die behandeling die verlangde effek het. Indien u dokter u inlig om u behandeling te staak met **VILDAMET** weens lewerprobleme, moet u nooit weer **VILDAMET** neem nie.

Indien u vrae het omtrent hoe lank u **VILDAMET** moet neem, raadpleeg u dokter.

Indien u meer VILDAMET geneem het as wat u moes

Ingeval van oordosering, raadpleeg u dokter of apteker. Indien albei nie beskikbaar is nie, kry hulp by die naaste hospitaal of vergiftingsentrum.

Indien u ernstige duiseligheid, ongereëlde hartklop of vinnige asemhaling ondervind weens lae bloedsuiker, is hemodialise nodig deur ‘n gesondheidsorgpersoon, met die toepaslike ondersteunende behandeling wat gedoen moet word volgens die pasiënt se kliniese tekens en simptome.

Indien u vergeet het om VILDAMET te neem

Dit word aanbeveel dat u die medisyne neem op dieselfde tyd elke dag. Indien u vergeet het om **VILDAMET** te neem, neem dit so gou as wat u onthou en neem dan die volgende dosis op sy gewone tyd. As dit egter amper tyd is vir u volgende dosis,

slaan die dosis oor wat u gemis het. Moenie ‘n dubbele dosis neem om op te maak vir die tablet wat u vergeet het nie.

4. Moontlike newe-effekte

VILDAMET kan newe-effekte hê.

Nie alle newe-effekte gerapporteer vir **VILDAMET** is ingesluit in hierdie biljet nie.

Indien u algemene gesondheid agteruitgaan of indien u enige ongewenste effekte ondervind terwyl u hierdie medisyne neem, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgpersoon vir advies.

Indien enige van die volgende gebeur, staak die gebruik van **VILDAMET** en vertel u dokter onmiddellik of gaan na die ongevalle afdeling by u naaste hospitaal:

• Opgeswelde gesig, tong of keel, probleme om te sluk, asemhalingsprobleme, skielike begin van uitslag of netelroos (simptome van ernstige allergiese reaksie wat genoem word ‘angio-edeem’).

Hierdie is almal baie ernstige newe-effekte. Indien u dit het, het u ‘n ernstige allergiese reaksie gehad met **VILDAMET**. U kan moontlik dringende mediese aandag of hospitalisering benodig.

Vertel u dokter onmiddelik of gaan na die ongevalle departement by u naaste hospitaal indien u enige van die volgende opmerk:

• Gevoel van koue en ongemak, spierpyn, lomerigheid, ernstige naarheid of braking, abdominale pyn, onverklaarbare massaverlies, duiseligheid, ongereëlde hartklop, of vinnige asemhaling (simptome van laktiese asidose). Indien dit gebeur, moet u die gebruik van **VILDAMET** staak en u ‘n dokter of die naaste hospitaal onmiddellik kontak, omdat laktiese asidose koma tot gevolg kan hê.

Hierdie is almal baie ernstige newe-effekte. U kan dringende mediese sorg benodig.

Vertel u dokter indien u enige van die volgende opmerk:

Sommige pasiënte het die volgende newe-effekte gehad terwyl hulle **VILDAMET** geneem het:

Dikwelse Newe-effekte:

- Opswel van die keel en neuskanale
- Gevoel van duiseligheid, hoofpyn of onwillekeurige bewerigheid
- Naarheid, braking, diarree, refluks, winderigheid, hardlywigheid of pyn in die abdomen
- Oormatige sweet, jeukerigheid, uitslag, rooiheid of afdop van vel
- Pyn in die spiere of uitputting
- Laktiese asidose (simptome gemeld hierbo)

Minder Dikwelse Newe-effekte:

- Lae bloedsuiker, verlies van aptyt, afname in die vlak van vitamien B12 in die bloed (anemie)
- Metaal smaak in die mond
- Inflammasie of siekte van pankreas
- Inflammasie of siekte van lewer
- Pyn in gewrigte of spiere
- Uitputting, koue, geswelde hande, enkels of voete (edeem)
- Abnormale lewerfunksie toetsresultate

Newe-effekte Frekwensie Onbekend:

- Plaaslike afdop van vel of blasies.

Indien u enige ander newe-effekte opmerk wat nie gemeld is in hierdie biljet nie, stel asseblief u dokter of apteker in kennis daarvan.

Rapporteer van newe-effekte

Indien u newe-effekte kry, raadpleeg u dokter, apteker of verpleegkundige.

U kan newe-effekte ook rapporteer aan SAHPRA via die "**6.04 Adverse Drug Reaction Reporting Form**", wat aanlyn gevind word onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte te rapporteer kan u help om meer inligting te voorsien omtrent die veiligheid van **VILDAMET**.

5. Hoe om VILDAMET te berg

• Berg by of benede 30 °C in die oorspronklike verpakking.

• Beskerm teen vog. Moenie verwyder uit die oorspronklike verpakking nie totdat dit nodig is vir gebruik.

• Moenie gebruik na die vervaldatum wat op die houer gewys word nie.

• Moenie enige **VILDAMET** pak gebruik wat beskadig is of wat tekens wys dat daaraan gepeuter is nie.

• Hou buite die bereik van kinders.

6. Inhoud van die pakkie en ander inligting

Elke **VILDAMET** 50 / 850 mg tablet bevat 50 mg vildagliptien en 850 mg metformienhidrochloried.

Elke **VILDAMET** 50 / 1000 mg tablet bevat 50 mg vildagliptien en 1 000 mg metformienhidrochloried.

Die ander bestanddele is:

Etanol, Hidroksipropielsellulose, Mikrokristallynsellulose (PH-101 en PH-102), Magnesiumstearaat, Opadry AMB II Geel (kleurstof) en Povidoon K90.

Opadry AMB II Geel bestanddele: Gliserol van FA, Ysteroksied geel, Poliviniel alkohol (gehidroliseer), Natriumlourielsulfaat, Talk en Titaniumdioksied.

Hoe VILDAMET lyk en inhoud van die pakkie

VILDAMET 50 mg/ 850 mg filmbedekte tablette:

Geel gekleurde ovaloïed-vormige tablette glad aan beide kante.

VILDAMET 50 mg/ 1000 mg filmbedekte tablette: Donkergeel gekleurde ovaloïed-vormige tablette glad aan beide kante.

VILDAMET filmbedekte Tablette is beskikbaar in ‘n Alu-Alu stolppak van 10 tablette wat verpak word in ‘n gedrukte kartongrootte 3 x 10 saam met die voubiljet in die gedrukte karton.

Houer van Sertifikaat van Registrasie

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Johannesburg

2092

Suid-Afrika

Hierdie biljet was hersien in

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Registrasienommers

VILDAMET 50/850: 59/21.2/0253

VILDAMET 50/1000: 59/21.2/0254

Toegang tot die ooreenstemmende Professionele Inligting. Volg die skakel vir die ooreenstemmende Professionele Inligting vir **VILDAMET**: pi-pil-repository.innovata.co.za, alternatief skandeer asseblief die QR kode hieronder: