PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

[PRODUCT NAME] 50/850 film-coated tablets

[PRODUCT NAME] 50/1000 film-coated tablets

Vildagliptin and metformin hydrochloride

Sugar free

Read all of this leaflet carefully before you start taking [PRODUCT NAME]

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist, nurse or other health care provider.
- **[PRODUCT NAME]** 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 **[PRODUCT NAME]** is and what it is used for
2. What you need to know before you take **[PRODUCT NAME]**
3. How to take **[PRODUCT NAME]**
4. Possible side effects
5. How to store **[PRODUCT NAME]**
6. Contents of the pack and other information

1. WHAT [PRODUCT NAME] IS AND WHAT IT IS USED FOR

[PRODUCT NAME] contains two active substances, vildagliptin and metformin, belong to a group of medicines called “oral antidiabetics”.

[PRODUCT NAME] is a medicine used to treat type 2 diabetes. **[PRODUCT NAME]** helps to control the level of sugar in the blood.

Your doctor has prescribed **[PRODUCT NAME]** 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.

[PRODUCT NAME] 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.

[PRODUCT NAME] can also be prescribed for you as add-on to insulin if your blood sugar level 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 **[PRODUCT NAME]**.

Ask your doctor if you have any questions about why **[PRODUCT NAME]** has been prescribed for you.

2.WHAT YOU NEED TO KNOW BEFORE YOU TAKE [PRODUCT NAME]

Do not take [PRODUCT NAME] if:

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

• if you have a problem with your kidneys

• if you have liver problems

• if you have recently had a heart attack, have heart failure, or if you have severe circulatory problems, including shock or breathing difficulties

Warnings and precautions

Take special care with [PRODUCT NAME]:

• **[PRODUCT NAME]** is not a substitute for insulin. You should therefore neither receive **[PRODUCT NAME]** for the treatment of Type I 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, get medical help immediately. Patients taking metformin 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 functioning 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 **[PRODUCT NAME]** alone).

• if you have any heart disease

• if you are going to have an operation under general anaesthetic, you may need to stop taking **[PRODUCT NAME]** for a couple of days before and after the procedure.

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

• If you have a liver disease.

• 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 **[PRODUCT NAME]** 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

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 **[PRODUCT NAME]** because of liver problems, you should never start taking **[PRODUCT NAME]** again.

• a general blood test at least once a year

• a check of Vitamin B12 levels at least every two to three years

Children and adolescents

The use of **[PRODUCT NAME]** in children and adolescents up to 18 years of age is not recommended.

Other medicines and [PRODUCT NAME]

Always tell your health care provider if you are taking any other medicine (This includes all complementary or traditional medicines).

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 **[PRODUCT**

NAME] before or at the time of the injection. Your doctor will decide when you must stop and when to restart your treatment with **[PRODUCT NAME]**.

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. You may need more frequent blood glucose and kidney function tests, or your doctor may need to adjust the dosage of **[PRODUCT NAME]**. It is especially important to mention the following:

- Furosemide, a water tablet used to control blood pressure
  Certain medicines used to treat infections (e.g. vancomycin, trimethoprim)
- Beta-2 agonists generally used to treat respiratory disorders
- Certain medicines used to treat diabetes (e.g. glibenclamide, pioglitazone, metformin hydrochloride)
- Certain medicines used to treat inflammation (e.g. corticosteroids)
- Certain medicines used to treat high blood pressure (e.g. amiloride, triamterene, nifedipine, diuretics, ACE inhibitors such as captopril, enalapril)
- Certain medicines used to treat irregular heartbeat (e.g. digoxin, quinidine)
- Certain medicines used to reduce pain (e.g. morphine)
- 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)

[PRODUCT NAME] with food, drink and alcohol

Avoid excessive alcohol intake while taking **[PRODUCT NAME]** since this may increase the risk of lactic acidosis (see Warnings and precautions).

[PRODUCT NAME] and older people

Your doctor should check the function of your kidneys several times a year if you are elderly. Your dose will be adjusted based on your renal function.

Pregnancy, breastfeeding and fertility

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.

Safety in pregnancy and breastfeeding has not been established.

You should not take **[PRODUCT NAME]** when you are pregnant or breastfeeding your infant.

If you are taking **[PRODUCT NAME]** you should not breastfeed your baby.

Your doctor will discuss with you the potential risk of taking **[PRODUCT NAME]** during pregnancy.

Driving and using machines

It is not always possible to predict to what extent [PRODUCT NAME] may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which [PRODUCT NAME] affects you.

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

3.HOW TO TAKE [PRODUCT NAME]

Do not share medicines prescribed for you with any other person.

Always take **[PRODUCT NAME]** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

If you get the impression that the effect of **[PRODUCT NAME]** is too strong or too weak, tell your doctor or pharmacist.

The recommended dose is one tablet of either 50 mg/850 mg or 50 mg/1000 mg taken twice a day.

Your doctor will tell you exactly how many tablets of **[PRODUCT NAME]** to take. Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.

Do not take more **[PRODUCT NAME]** than your doctor has prescribed.

[PRODUCT NAME] 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.

If your doctor tells you to stop your treatment with **[PRODUCT NAME]** because of liver problems, you should never start taking **[PRODUCT NAME]** again.

If you have questions about how long to take **[PRODUCT NAME]**, talk to your doctor.

If you take more [PRODUCT NAME] than you should

If you take too many tablets, or if someone else has taken your medicine, tell a doctor straight away. You may require medical attention. Show the doctor the pack if possible.

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 forget to take [PRODUCT NAME]

It is advisable to take your medicine at the same time each day. If you forget to take **[PRODUCT NAME]**, 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.

If you stop taking [PRODUCT NAME]

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 **[PRODUCT NAME]** unless your doctor tells you to. If you have any questions about how long to take this medicine, talk to your doctor.

4.POSSIBLE SIDE EFFECTS

[PRODUCT NAME] can have side effects.

Not all side effects reported for **[PRODUCT NAME]** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **[PRODUCT NAME]** please consult your health care provider for advice.

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

- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (angioedema)
- Swelling of hands, ankles or feet (Oedema peripheral)

- Skin rashes or itching (pruritus)
- Itchy rash (urticaria)

These are all very serious side effects. If you have them, you may have had a serious reaction to **[PRODUCT NAME]**. 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)
- A liver disease; symptoms include nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, light coloured bowel (hepatitis)
- inflammation of the pancreas; symptoms include severe upper stomach pain, often with nausea and vomiting (pancreatitis)
- irregular heart beat or deep, rapid breathing
- severe muscle aching or swelling, especially in the shoulders, thighs or lower back.
- muscle weakness or stiffness, or trouble moving arms or legs.
- dark red or brown urine, or reduced or no urine output. confusion, dehydration or fever.
- lack of consciousness.

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

Tell your doctor if you notice any of the following:

<u>Frequent side effects:</u>

- Shaking or tremors
- Dizziness
- Headache, chills
- Feeling sick (nausea)

- Low sugar (glucose) levels in the blood; symptoms include sweating, weakness, hunger, dizziness, trembling, headache, flushing or paleness, numbness, having a fast, pounding heart beat
- Excess amount of gastric juice flowing back (refluxes) into the oesophagus (gullet or the tube that goes from mouth to stomach through which food passes), causing heartburn and possibly damaging the oesophagus
- Excessive sweating
- Unusual weakness
- Pain in and around the stomach, vomiting
- Loss of appetite.
- Metallic taste

Less frequent side effects:

- Fatigue
- Diarrhoea
- Wind
- Upper respiratory tract infections with symptoms such as sore throat and runny nose
- Constipation
- Joint pain
- Decreased vitamin B_{12} levels (paleness, tiredness, mental symptoms such as confusion or memory disturbances
- Abnormal liver function test results.
- Redness of the skin

Frequency not known

- Localised peeling of skin or blisters,
- Muscle pain

If you notice any 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 or pharmacist. You can also report side effects to SAHPRA via the Adverse drug reaction and quality problem reporting form", found online under SAHPRA's publications: https://www.sahpra.org.za/documents/adverse-drug -reactions-and-quality-problem-reporting-form/

By reporting side effects, you can help provide more information on the safety of **[PRODUCT NAME]**.

5.HOW TO STORE [PRODUCT NAME]

Store all medicines out of reach of children.

- Store at or below 25 ^{0}C
- Store in the original package / container
- Protect from light / moisture
- Do not store in a bathroom
- Do not use after the expiry date stated on the label / carton / bottle
- There are no special storage instructions for **[PRODUCT NAME]**.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6.CONTENTS OF THE PACK AND OTHER INFORMATION

What [PRODUCT NAME] contains

The active substances for **[PRODUCT NAME]** are vildagliptin and metformin hydrochloride.

[PRODUCT NAME] 50/850

Each film coated tablet contains:

Vildagliptin 50 mg and Metformin Hydrochloride 850 mg.

Sugar Free

[PRODUCT NAME] 50/1000

Each film coated tablet contains:

Vildagliptin 50 mg and Metformin Hydrochloride 1000 mg.

Sugar Free

The other ingredients are:

Tablet core

Hyroxypropylcellulose, Magnesium Stearate (vegetable origin) and Purified Water.

Film coating

Opadry® White (YS-1-7040) and Purified Water.

What [PRODUCT NAME] looks like and contents of the pack

[PRODUCT NAME] 50/850

White to off white, film coated, oval shaped tablets debossed with 'VM2' on one side and plain on the other side.

[PRODUCT NAME] 50/1000

White to off white, film coated, oval shaped tablets debossed with 'VM1' on one side and plain on the other side.

Strip Pack

Hard tempered, heat sealable aluminium foil coated with HSL and of printable quality. Each strip will contain 10 tablets. Stips are packed in cartons of 30 or 60 tablets.

Cold Form Blister

Cold form laminate composed of aluminium foil one side bright, soft tampered, plain, dull side lacquer-laminated to oriented polyamide film bright side lacquer-laminated to PVC film. Each blister will contain 10 tablets. Blisters are packed in a carton in cartons of 30 or 60 tablets.

HOLDER OF CERTIFICATE OF REGISTRATION AND MANUFACTURER

Ranbaxy Pharmaceuticals (Pty) Ltd

a SUN PHARMA company

Roodepoort, 1724

South Africa

This leaflet was last revised in

To be allocated

Registration Number

[PRODUCT NAME] 50/850: Will be allocated by SAHPRA upon registration

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