Patient Information Leaflet

Proposed Patient Information Leaflet

SCHEDULING STATUS:

S3

VILEPTIN 50 Film coated tablets

(Vildagliptin)

Contains sugar: Lactose anhydrous 94,50 mg per tablet

Read all of this leaflet carefully before you start taking VILEPTIN

- 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.

VILEPTIN 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 VILEPTIN is and what it is used for

Each **VILEPTIN** tablet contains 50 mg of the active substance vildagliptin.

VILEPTIN is a medicine used to treat patients with type 2 diabetes whose condition cannot be controlled by diet and exercise alone. It helps to control the level of sugar in the blood. Such medicines are known as oral antidiabetics.

Vildagliptin helps to control the blood sugar by making the pancreas produce insulin and less glucagon. Vildagliptin helps to control your blood sugar level.

Your doctor has prescribed vildagliptin in combination with other antidiabetics depending on your condition. It is important that you continue to follow the diet and/or exercise advised for you, whilst you are on treatment with vildagliptin.

2. What you need to know before you take VILEPTIN

Do not take VILEPTIN if:

- if you are hypersensitive (allergic) to vildagliptin or any of the other ingredients of **VILEPTIN** tablets (listed in section 6).

  You have liver problems.

Warnings and precautions

Take special care with **VILEPTIN**:

- if you have kidney problems or if you are on dialysis. You may require a lower dose of **VILEPTIN**.
- if you suffer from heart failure. Your doctor will decide whether or not to prescribe **VILEPTIN** for you depending on the severity of your condition.
- if you have or have had a disease of the pancreas (i.e. developed severe stomach or abdominal pain). This may be an indication that your pancreas is affected by the medicine. If this occurs, the use of **VILEPTIN** must be stopped immediately and not to be taken again.
- if you are also taking an antidiabetic medicine known as a sulphonylurea. Sulphonylureas may cause your blood sugar level to become very low. Your doctor may want to lower the dose of your sulphonylurea when you take it together with **VILEPTIN** in order to avoid low blood sugar levels.

- you may experience joint pain, sometimes severe.
- if you have type 1 diabetes (i.e. your body does not produce insulin) or if you have a condition called diabetic ketoacidosis (a complication of diabetes causing rapid weight loss, nausea or vomiting). **VILEPTIN** should not be used to treat these conditions.
- if you develop any skin disorders such as blisters or ulcers. 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 vildagliptin. Should these occur, you should promptly consult your doctor.

Monitoring your VILEPTIN treatment:

Ensure that your doctor tests your blood and urine regularly for sugar.

Your liver function should be checked:

- at the start of treatment with **VILEPTIN** and
- every 3 months during the first year of treatment and regularly thereafter.

If your doctor told you to stop your treatment with vildagliptin because of liver problems, you should never start taking vildagliptin again.

Children and adolescents

Do not give **VILEPTIN** in children aged up to 18 years because the safety and efficacy of **VILEPTIN** in children aged up to 18 years have not been established.

Other medicines and VILEPTIN

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

The blood sugar lowering effect of **VILEPTIN** may be reduced if taken along with one of the following medicines:

- thiazides (used to control blood pressure, also called water tablets),
- corticosteroids (generally used to treat inflammation),
- thyroid products (used to treat conditions of the thyroid gland),
- certain medicines affecting the nervous system (sympathomimetics).

Taking **VILEPTIN** with medicines known as angiotensin converting enzyme (ACE)-inhibitors (used to treat high blood pressure), may lead to swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (angioedema).

VILEPTIN with food, drink and alcohol

VILEPTIN should be taken orally and can be taken with or without food.

Pregnancy, breast-feeding 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.

The safety of vildagliptin in pregnancy and breastfeeding has not been established.

You should not use **VILEPTIN** if you are pregnant.

Do not breastfeed your baby during treatment with **VILEPTIN**.

Driving and using machines

VILEPTIN may cause dizziness. If you feel dizzy while taking **VILEPTIN**, you should avoid driving vehicles or using machines.

It is not always possible to predict to what extent **VILEPTIN** 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 **VILEPTIN** affects you.

VILEPTIN contains lactose anhydrous

VILEPTIN contains lactose anhydrous. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take **VILEPTIN**.

3. How to take VILEPTIN

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

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

The usual dose is:

- 50 mg once a day - Take one tablet in the morning

  OR

- 50 mg twice a day - Take one tablet in the morning and one tablet in the evening

VILEPTIN can be taken with or without food.

Your doctor has prescribed **VILEPTIN** in combination with another antidiabetic if one medicine alone is not sufficient to control your blood sugar level.

The tablets should preferably be swallowed whole with some water. The tablets may be taken with or without food.

Elderly: No dosage adjustments are necessary for elderly patients who do not have kidney problems.

Patients with liver or kidney problems: The recommended dose for patient with moderate or severe kidney problems or who has end-stage renal disease and or who is on haemodialysis is 50 mg in the morning (1 tablet of **VILEPTIN**).

Children: **VILEPTIN** should not be used in children under 18 years of age.

If you take more VILEPTIN than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you have taken too much **VILEPTIN**, you may experience muscle pain, tingling or prickling sensation in hands and feet, fever, swelling

If you forget to take VILEPTIN

If you forget to take a dose of this medicine, take it as soon as you remember. Then take your next dose at the usual time. If it is almost time for your next dose, skip the dose you missed. Do not take a double dose to make up for a forgotten individual doses.

If you stop taking VILEPTIN

Continue taking **VILEPTIN** every day for as long as your doctor tells you.

You may have to stay on the treatment for a long period of time. Do not stop taking **VILEPTIN** unless your doctor tells you to. Your doctor will regularly monitor your blood sugar levels to determine if the treatment is having the desired effect. If your doctor has told you to stop your treatment with **VILEPTIN** because of liver problems you should never start taking **VILEPTIN** again. If you have questions about how long to take **VILEPTIN**, talk to your doctor.

Your doctor will tell you how long your treatment with **VILEPTIN** will last. If you have the impression that the effect of **VILEPTIN** is too strong or too weak, tell your doctor or pharmacist.

4. Possible side effects

VILEPTIN can have side effects.

Not all side effects reported for **VILEPTIN** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **VILEPTIN**, please consult your doctor, pharmacist or other healthcare provider for advice.

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

- Shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin (allergic reaction, angioedema).

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

- Liver disease (hepatitis): Symptoms include yellow skin and eyes, nausea (feeling sick), loss of appetite or light-coloured urine, which may indicate liver problem.
- 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.
- Localised peeling of skin or blisters

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

Tell your doctor if you notice any of the following:

<u>Frequent side effects:</u>

- Trembling, dizziness, headache, chills
- Weakness; swollen hands, ankle or feet
- Feeling sick, constipation, heartburn
- Low blood glucose (sugar) in the blood, weight increase
- Excessive sweating

Less frequent side effects:

- Infections of the upper respiratory tract for instance the nose, sinuses, throat and vocal cords (symptoms include sore throat, runny nose, fever)
- Tiredness
- Diarrhoea (loose stools), indigestion
- Joint pain

Frequency *unknown*:

- Abnormal liver function tests
- Muscle pain
- Itchy rash

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 or nurses. 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/document/adverse-drug-reactions-and-quality-problem-reporting-form/

By reporting side effects, you can help provide more information on the safety of **VILEPTIN**.

5. How to store VILEPTIN

Store all medicines out of reach of children.

6. Contents of the pack and other information

What VILEPTIN contains

The active substance is vildagliptin.

Each film coated tablet contains 50 mg vildagliptin

The other ingredients are: Lactose anhydrous, microcrystalline cellulose, sodium starch glycolate and magnesium stearate.

What VILEPTIN looks like and contents of the pack

White to off white colored, round tablets debossed with '50' on one side and 'V' on other side.

The tablets are packed in Cold form blister pack of 10’s (each blister contains 10 tablets).

Each carton can contain 3 x 10 or 6 x 10 blisters thus the pack sizes are:

30’s or 60’s.

Holder of Certificate of Registration

Ranbaxy Pharmaceuticals (Pty) Ltd

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South Africa

This leaflet was last revised in

Will be allocated by SAHPRA upon registration

Registration number

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