

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS

S3

**SITAGLIPTIN ZYDUS 25 film-coated tablets**

**SITAGLIPTIN ZYDUS 50 film-coated tablets**

**SITAGLIPTIN ZYDUS 100 film-coated tablets**

**Sitagliptin**

**Sugar free.**

### **Read all of this leaflet carefully before you start taking SITAGLIPTIN ZYDUS**

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

## 1. What SITAGLIPTIN ZYDUS is and what it is used for

**SITAGLIPTIN ZYDUS** contains the active substance sitagliptin which is a member of a class of medicines called dipeptidyl peptidase-4 (DPP-4) inhibitors that lowers blood sugar levels in adult patients with type 2 diabetes mellitus.

Your doctor has prescribed **SITAGLIPTIN ZYDUS** to help lower your blood sugar, which is too high because of your type 2 diabetes. **SITAGLIPTIN ZYDUS** helps to increase the levels of insulin produced in your body after a meal and decreases the amount of sugar made by your body.

**SITAGLIPTIN ZYDUS** can be used alone or in combination with certain other medicines that lower blood sugar, which you may already be taking for your diabetes, together with a diet and exercise plan.

### ***What is type 2 diabetes?***

Type 2 diabetes is a condition in which your body does not make enough insulin, and the insulin that your body produces does not work as well as it should. Your body can also make too much sugar. When this happens, sugar (glucose) builds up in your blood. This can lead to serious medical problems.

## 2. What you need to know before you take SITAGLIPTIN ZYDUS

### **Do not take SITAGLIPTIN ZYDUS**

- if you are hypersensitive (allergic) to sitagliptin or to any of the other ingredients of **SITAGLIPTIN ZYDUS** listed in section 6 of this leaflet;
- if you previously had an allergic reaction to any other medicine which is also a member of the class of medicines called dipeptidyl peptidase-4 (DPP-4) inhibitors;
- if you suffer from severe liver disease;

## Warnings and precautions

Take special care with:

- type 1 diabetes;
- a disease of the pancreas (such as pancreatitis);
- any kidney problems or a history of kidney problems;

Tell your doctor if you experience any of the following while taking **SITAGLIPTIN ZYDUS**:

- an allergic reaction (see section 4);
- inflammation of your pancreas (pancreatitis) (causing pain of your upper stomach area that radiates to your back, fever, nausea, vomiting and tenderness of your stomach area). Cases of pancreatitis have been reported in patients taking **SITAGLIPTIN ZYDUS**;
- if you encounter blistering of the skin, it may be a sign of a condition called bullous pemphigoid.

**SITAGLIPTIN ZYDUS** is unlikely to cause low blood sugar because it does not work when your blood sugar is low. However, when **SITAGLIPTIN ZYDUS** is used in combination with a sulphonylurea medicine or with insulin, low blood sugar (hypoglycaemia) can occur. Your doctor may reduce the dose of your sulphonylurea or insulin medicine.

## ***Children and adolescents***

**SITAGLIPTIN ZYDUS** is not recommended for use in children and adolescents under 18 years of age.

## **Other medicines and SITAGLIPTIN ZYDUS**

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

Tell your doctor if you are taking digoxin (used to treat an irregular heart beat or other heart problems). Your doctor may have to check the level of digoxin in your blood if you are taking **SITAGLIPTIN ZYDUS**.

### **SITAGLIPTIN ZYDUS with food and drink**

See section 3.

### **Pregnancy and breastfeeding**

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 healthcare provider for advice before taking **SITAGLIPTIN ZYDUS**.

If you are pregnant or breastfeeding your baby, you should not use **SITAGLIPTIN ZYDUS**.

### **Driving and using machines**

**SITAGLIPTIN ZYDUS** has no or negligible influence on the ability to drive and use machines.

However, **SITAGLIPTIN ZYDUS** can cause side effects, such as dizziness or drowsiness. You should not drive a vehicle, or operate machinery until you know how **SITAGLIPTIN ZYDUS** affects you.

Taking **SITAGLIPTIN ZYDUS** in combination with medicines called sulphonylureas or with insulin can cause hypoglycaemia (low blood sugar), which may affect your ability to drive and use machines or work without safe foothold.

## **3. How to take SITAGLIPTIN ZYDUS**

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

Always take or give **SITAGLIPTIN ZYDUS** exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is 100 mg once daily when used with other medicines that are used to treat

diabetes.

Your doctor may adjust your dose if you have kidney problems.

Your doctor will tell you how long your treatment with **SITAGLIPTIN ZYDUS** will last. Do not stop treatment with **SITAGLIPTIN ZYDUS** unless your doctor tells you to.

**SITAGLIPTIN ZYDUS** can be taken with or without food.

If you have the impression that the effect of **SITAGLIPTIN ZYDUS** is too strong or too weak, tell your doctor or pharmacist.

#### **If you take more SITAGLIPTIN ZYDUS than you should**

In the event of overdosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison centre. You or a child in your care may require medical attention. Take the medicine pack with you.

#### **If you forget to take SITAGLIPTIN ZYDUS**

If you forget a dose, take it as soon as you remember. However if it is nearly time for the next dose, skip the missed dose. Then continue with your normal schedule. Do not take a double dose to make up for a forgotten dose.

#### **4. Possible side effects**

**SITAGLIPTIN ZYDUS** can have side effects.

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

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

- swelling of your hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing;
- rash, hives or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to **SITAGLIPTIN ZYDUS**. 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:*

- severe and persistent pain in the abdomen (stomach area) which might reach through to your back with or without nausea and vomiting, as these could be signs of an inflamed pancreas (pancreatitis);
- severe blistering skin rash, known as Stevens-Johnson syndrome or bullous pemphigoid;
- reduced number of platelets in your blood (which can affect clotting and cause unexplained bleeding or bruising);
- difficulty breathing due to scarring of your lung tissues;
- kidney problems (shortness of breath, more or less urine than is normal for you, confusion, drowsiness).

*Tell your doctor if you notice any of the following:*

*Frequent side effects:*

- headache.

*Less frequent side effects:*

- dizziness;
- constipation.

*The following side effects may occur, but the frequency is unknown:*

- upper respiratory tract infections, stuffy or runny nose and sore throat;
- vomiting (being sick);
- joint pain, muscle pain, back pain or joint degeneration.

The following side effects may occur when **SITAGLIPTIN ZYDUS** is used with other diabetic medicines:

*Side effects which occur frequently when using **SITAGLIPTIN ZYDUS** with sulphonylurea and metformin:*

- low blood sugar (dizziness, light-headedness);
- constipation.

*Side effects which occur frequently when using **SITAGLIPTIN ZYDUS** with insulin:*

- flu.

*Side effects which occur less frequently when using **SITAGLIPTIN ZYDUS** with insulin (with or without metformin):*

- dry mouth.

*Side effects which occur frequently when using **SITAGLIPTIN ZYDUS** with metformin:*

- nausea (feeling sick);
- vomiting (being sick);
- flatulence (excessive wind).

*Side effects which occur less-frequently when using **SITAGLIPTIN ZYDUS** with metformin:*

- drowsiness;
- diarrhoea.

*Side effects which occur frequently when using **SITAGLIPTIN ZYDUS** with pioglitazone:*

- flatulence (excessive wind);
- swelling of your hands, feet, arms or legs due to water retention.

*Side effects which occur frequently when using **SITAGLIPTIN ZYDUS** with pioglitazone and metformin:*

- swelling of your hands, feet, arms or legs due to water retention.

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. This includes any possible side effects not listed in this leaflet. 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 **SITAGLIPTIN ZYDUS**.

### **5. How to store SITAGLIPTIN ZYDUS**

- Store at or below 25 °C.
- Keep the blister strips in the outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton or container.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).



## 6. Contents of the pack and other information

### What SITAGLIPTIN ZYDUS contains

The active substance in **SITAGLIPTIN ZYDUS** is sitagliptin.

**SITAGLIPTIN ZYDUS 25:** Each film-coated tablet 25 mg sitagliptin.

**SITAGLIPTIN ZYDUS 50:** Each film-coated tablet 50 mg sitagliptin.

**SITAGLIPTIN ZYDUS 100:** Each film-coated tablet 100 mg sitagliptin.

The other ingredients are:

#### *Tablet core:*

Colloidal silicon dioxide (E551)

Croscarmellose sodium (E468)

Dibasic calcium phosphate (E341)

Magnesium stearate (E572)

Malic acid (E296)

Microcrystalline cellulose (E460)

Povidone (E1201)

#### *Film-coating:*

##### **SITAGLIPTIN ZYDUS 25:**

Opadry white (containing macrogol (E1521), polyvinyl alcohol (E1203), talcum (E553b), titanium dioxide (E171))

##### **SITAGLIPTIN ZYDUS 50:**

Opadry yellow (containing ferrousferic oxide (E172), iron oxide yellow (E172), macrogol (E1521), polyvinyl alcohol (E1203), talcum (E553b), titanium dioxide (E171))

##### **SITAGLIPTIN ZYDUS 100:**

Opadry beige (containing FD&C yellow (E110), iron oxide yellow (E172), macrogol (E1521), polyvinyl alcohol (E1203), talcum (E553b), titanium dioxide (E171))

### **What SITAGLIPTIN ZYDUS looks like and contents of the pack**

**SITAGLIPTIN ZYDUS 25:** White to off-white, round, biconvex, film-coated tablets, debossed with '12' on one side and '40' on the other side.

**SITAGLIPTIN ZYDUS 50:** Pale yellow coloured, round, biconvex, film-coated tablets, debossed with '12' on one side and '41' on the other side.

**SITAGLIPTIN ZYDUS 100:** Beige coloured, round, biconvex, film-coated tablets, debossed with '12' on one side and '42' on the other side.

Aluminium/aluminium blister strip containing 10 film-coated tablets packed into an outer carton.

Pack size: 30 tablets.

### **Holder of certificate of registration**

Zydus Healthcare SA (Pty) Ltd

Southdowns Office Park

Building B, Ground Floor

22 Karee Street

Centurion, Pretoria

0157

### **This leaflet was last revised in**

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