

## Patient Information Leaflet

**SCHEDULING STATUS:** **S4**

**ZITAGLUC PLUS 50/500** (Film coated tablets)

**ZITAGLUC PLUS 50/850** (Film coated tablets)

**ZITAGLUC PLUS 50/1000** (Film coated tablets)

**(Sitagliptin/Metformin)**

**Sugar Free**

**Read all of this leaflet carefully before you are given ZITAGLUC PLUS.**

- 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.

ZITAGLUC PLUS 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 ZITAGLUC PLUS is and what it is used for
2. What you need to know before you take ZITAGLUC PLUS
3. How to take ZITAGLUC PLUS
4. Possible side effects
5. How to store ZITAGLUC PLUS
6. Contents of the pack and other information

## **1) What ZITAGLUC PLUS is and what it is used for**

ZITAGLUC PLUS is a tablet that contains two prescription medicines, sitagliptin and metformin, which lower blood sugar levels. Sitagliptin, a member of a class of medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors) and metformin, a member of the biguanide class of medicines, work together to control blood sugar levels in patients with type 2 diabetes mellitus. Type 2 diabetes is also called non-insulin-dependent diabetes mellitus or NIDDM.

Along with diet and exercise, this medicine helps lower your blood sugar. This medicine can be used alone or with certain other medicines for diabetes (insulin, sulphonylureas, or glitazones).

Your doctor has prescribed ZITAGLUC PLUS, along with diet and exercise, to help lower your blood sugar levels.

If you have any questions about how ZITAGLUC PLUS works or why this medicine has been prescribed for you, ask your doctor.

## **2) What you need to know before you take ZITAGLUC PLUS**

### **DO NOT TAKE ZITAGLUC PLUS:**

- If you have certain kidney problems
- If you have recently had a heart attack or have severe circulatory problems, such as 'shock' or breathing difficulties.
- If you are allergic to sitagliptin, metformin hydrochloride or any other components of ZITAGLUC PLUS

- If you are going to get or receive an injection of dye or contrast agent for an x-ray procedure. Talk to your doctor about when to stop ZITAGLUC PLUS and when to start again.
- If you have uncontrolled diabetes, with e.g. severe hyperglycaemia (high blood glucose), nausea, vomiting, diarrhoea, rapid weight loss, lactic acidosis (see “Risk of lactic acidosis” below) or ketoacidosis. Ketoacidosis is a condition in which substances called ‘ketone bodies’ accumulate in the blood and which can lead to diabetic pre-coma. Symptoms include stomach pain, fast and deep breathing, sleepiness or your breath developing an unusual fruity smell.
- If you are breast-feeding
- If you have liver problems
- If you drink alcohol to excess (either every day or only from time to time)

### Warnings and precautions

**Hypersensitivity Reactions: There have been post-marketing reports of serious hypersensitivity reactions in patients treated with sitagliptin, one of the components of ZITAGLUC PLUS. These reactions include an acute life threatening hypersensitivity disorder, swelling under the skin and shedding of the skin conditions including Stevens-Johnson syndrome (rare serious disorder of the skin and mucous membrane, a reaction to medication that start with flu-like symptoms followed by a painful rash that spreads and blisters). Onset of these reactions occurred within the first 3 months after initiation of treatment with sitagliptin, with some reports occurring after the first dose. If a hypersensitivity reaction is suspected, discontinue combination of sitagliptin and metformin immediately, and institute an alternative class of medicines for treatment for diabetes.**

**Talk to your doctor, pharmacist or nurse before taking ZITAGLUC PLUS:**

- If you have kidney problems
- If you have type 1 diabetes. This is sometimes called insulin-dependent diabetes
- If you have liver problems
- If you have heart problems
- If you are older than 80 years. Patients over 80 years should not take ZITAGLUC PLUS unless their kidney function is checked and it is normal.
- If you drink alcohol a lot (all the time or short-term “binge” drinking)
- If you have or have had an allergic reaction to sitagliptin, metformin, or ZITAGLUC PLUS
- If you encounter blistering of the skin it may be a sign for a condition called bullous pemphigoid.
- If you are taking a sulphonylurea or insulin, diabetes medicines, together with ZITAGLUC PLUS, as you may experience low blood sugar levels (hypoglycaemia). Your doctor may reduce the dose of your sulphonylurea or insulin

*Risk of lactic acidosis*

ZITAGLUC PLUS may cause a very rare, but very serious side effect called lactic acidosis, particularly if your kidneys are not working properly. The risk of developing lactic acidosis is also increased with uncontrolled diabetes, serious infections, prolonged fasting or alcohol intake, dehydration (see further information below), liver problems and any medical conditions in which a part of the body has a reduced supply of oxygen (such as acute severe heart disease). If any of the above apply to you, talk to your doctor for further instructions.

Stop taking ZITAGLUC PLUS and contact a doctor or the nearest hospital immediately if you experience some of the symptoms of lactic acidosis, as this condition may lead to coma. Symptoms of lactic acidosis include:

- Vomiting
- Stomach ache (abdominal pain)
- Muscle cramps
- A general feeling of not being well with severe tiredness
- Difficulty in breathing
- Reduced body temperature and heartbeat

Lactic acidosis is a medical emergency and must be treated in a hospital.

Pancreatitis (inflammation of the pancreas) can be a serious, potentially life-threatening medical condition. Stop taking ZITAGLUC PLUS and call your doctor if you experience severe and persistent stomach pain, with or without vomiting, because you could have pancreatitis.

If you need to have major surgery you must stop taking ZITAGLUC PLUS during and for some time after the procedure. Your doctor will decide when you must stop and when to restart your treatment with ZITAGLUC PLUS.

During treatment with ZITAGLUC PLUS, your doctor will check your kidney function at least once a year or more frequently if you are elderly and/or if you have worsening kidney function.

### **Children and adolescents**

ZITAGLUC PLUS has not been studied in children under 18 years of age.

### **Use in the elderly**

ZITAGLUC PLUS should be used with caution as age increases. Care should be taken in dose selection and should be based on careful and regular monitoring of renal function.

## **Other medicines and ZITAGLUC PLUS**

Always tell your health care provider if you are taking any other medicine (This includes all complementary or traditional medicines). If they are taken with ZITAGLUC PLUS their effect or the effect of ZITAGLUC PLUS may be changed.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Medicines (taken by mouth, inhalation, or injection) used to treat diseases that involve inflammation, like asthma and arthritis (corticosteroids)
- Medicines which increase urine production (diuretics)
- Medicines used to treat pain and inflammation (NSAID and COX-2-inhibitors, such as ibuprofen and celecoxib)
- Certain medicines for the treatment of high blood pressure (ACE inhibitors and angiotensin II receptor antagonists)
- Specific medicines for the treatment of bronchial asthma ( $\beta$ -sympathomimetics)
- Iodinated contrast agents or alcohol-containing medicines
- Certain medicines used to treat stomach problems such as cimetidine
- Vandetanib, a medicine used to treat a specific type of thyroid cancer (medullary thyroid cancer)
- Digoxin (to treat irregular heartbeat and other heart problems). The level of digoxin in your blood may need to be checked if taking with ZITAGLUC PLUS.
- Nifedipine (calcium channel blocker medication used to manage angina, high blood pressure)
- Amiloride (medications to treat high blood pressure or swelling due to heart failure or cirrhosis of the liver).
- Morphine (pain medication)

- Procainamide, quinidine (medication of the antiarrhythmic class used for the treatment of cardiac arrhythmias).
- Quinine (used to treat malaria and babesiosis)
- Ranitidine (medication that decreases stomach acid production)
- Trimethoprim or vancomycin (antibiotic used mainly in the treatment of several infections)

**ZITAGLUC PLUS with food and drink:**

Take ZITAGLUC PLUS with meals to lower your chance of an upset stomach.

**Pregnancy, breast-feeding and fertility:**

If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you might get pregnant, you should use a reliable method of contraception during treatment with ZITAGLUC PLUS.

If you are breast-feeding, tell your doctor. You should not breast-feed during treatment with ZITAGLUC PLUS.

**Driving and using machines:**

ZITAGLUC PLUS has no or negligible influence on the ability to drive and use machines. However, dizziness and drowsiness have been reported with sitagliptin, which may affect your ability to drive or use machines.

Taking this medicine in combination with medicines called sulphonylureas or with insulin can cause hypoglycaemia, which may affect your ability to drive and use machines or work without safe foothold.

### **3) How to take ZITAGLUC PLUS**

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

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Take one tablet:

- Twice daily by mouth
  - With meals to lower your chance of an upset stomach.
  - Your doctor may need to increase your dose to control your blood sugar.
- If you have reduced kidney function, your doctor may prescribe a lower dose.
- You should continue the diet recommended by your doctor during treatment with this medicine and take care that your carbohydrate intake is equally distributed over the day.

This medicine alone is unlikely to cause abnormally low blood sugar (hypoglycaemia). When this medicine is used with a sulphonylurea medicine or with insulin, low blood sugar can occur and your doctor may reduce the dose of your sulphonylurea or insulin.

Your doctor will determine the appropriate dose you need to take, as well as if and when you need to stop treatment with ZITAGLUC PLUS.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**Method of administration**

Take ZITAGLUC PLUS with meals to lower your chance of an upset stomach.

**If you take more ZITAGLUC PLUS than you should:**

If you take more than the prescribed dosage of this medicine, contact your doctor immediately. Go to the hospital if you have symptoms of lactic acidosis such as feeling cold or uncomfortable, severe nausea or vomiting, stomach ache, unexplained weight loss, muscular cramps, or rapid breathing.

**If you forget to take ZITAGLUC PLUS:**

Do not worry. If you remember later on that day, take that day's dose as usual. If you miss a whole day's dose take the normal dose on the next day. Do not take a double dose to make up for a forgotten tablet. If you are not sure ask your doctor or pharmacist.

**If you stop taking ZITAGLUC PLUS:**

Continue to take this medicine as long as your doctor prescribes it so you can continue to help control your blood sugar. You should not stop taking this medicine without talking to your doctor first. If you stop taking ZITAGLUC PLUS, your blood sugar may rise again.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

**4) Possible side effects**

ZITAGLUC PLUS can have side effects.

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

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

- 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).
- Lactic acidosis (lactic acid build up in the bloodstream)
- If you have a serious allergic reaction, including rash, hives, blisters on the skin/peeling skin and swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing, stop taking this medicine and call your doctor right away. Your doctor may prescribe a medicine to treat your allergic reaction and a different medicine for your diabetes

These are all very serious side effects. If you have them, you may have had a serious reaction to ZITAGLUC PLUS. You may need urgent medical attention or hospitalisation.

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

**Frequent side effects:**

- Nausea
- Flatulence
- Vomiting
- Constipation
- Metallic taste (An altered or impaired sense of taste)
- Abdominal pain and loss of appetite

**Less frequent side effects:**

- Low blood sugar
- Somnolence
- Diarrhoea,
- A low number of platelets in the blood (thrombocytopenia)
- A group of disorders that cause progressive scarring of lung tissue (interstitial lung disease)
- Joint pain (Arthralgia)
- Muscle pain (myalgia)
- Pain in extremity
- Back pain
- A disease or abnormality of a joint (arthropathy)
- Impaired or acute renal function
- Increase in white blood cell count
- Decrease of vitamin B12 and folic acid absorption
- Headache
- Dizziness
- Redness of the skin, either in a limited area or all over (Mild erythema)
- Upper abdominal pain
- Acute inflammation of the pancreas(pancreatitis)
- Itching
- Swelling under the skin
- Rash
- Raised or puffy areas of the skin that itch intensely

- Inflammation of blood vessels which can restrict blood flow
- Immune system attacks a thin layer of tissue below your other layer of skin (Bulleous pemphigoid)

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 nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ZITAGLUC PLUS.

### **5) How to store ZITAGLUC PLUS**

Store all medicines out of reach of children.

- Store at or below 25 °C in the original package, protected from light and moisture.
- Do not remove the blisters from the carton until required for use.
- Remove your ZITAGLUC PLUS from the blister only immediately prior to intake.
- Do not take ZITAGLUC PLUS after the expiry date stated on the blister strips and carton.
- Return all unused or expired medicines to your pharmacist for safe disposal.
- Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

### **6) Contents of the pack and other information**

#### **What ZITAGLUC PLUS contains**

- The active ingredients is Sitagliptin and Metformin

**ZITAGLUC PLUS 50/500**

Light pink to pink, Capsule shaped film-coated tablets debossed with “SC5” on one side.

**ZITAGLUC PLUS 50/850**

Pink, Capsule shaped film-coated tablets debossed with “SC1” on one side.

**ZITAGLUC PLUS 50/1000**

Brown to Reddish brown, Capsule shaped film-coated tablets debossed with “SC7” on one side.

The other ingredients are:

Hydroxypropyl cellulose, Anhydrous Calcium hydrogen phosphate, Crospovidone, Hydrogenated Castor Oil, Glycerol dibehenate, and Magnesium stearate.

**Film coating**

Opadry® Complete film coating system 20A540048 Pink,

Opadry® Complete film coating system 20A540053 Pink,

Opadry® Complete film coating system 20A565037 Brown,

Isopropyl Alcohol and Methylene Chloride

**What ZITAGLUC PLUS looks like and contents of the pack****ZITAGLUC PLUS 50/500**

Light pink to pink, Capsule shaped film-coated tablets debossed with “SC5” on one side.

**ZITAGLUC PLUS 50/850**

Pink, Capsule shaped film-coated tablets debossed with “SC1” on one side.

**ZITAGLUC PLUS 50/1000**

Brown to Reddish brown, Capsule shaped film-coated tablets debossed with “SC7” on one side.

The product can be supplied in pack sizes of 28's, 30's, 56's, 60's and 200's comprising of an HDPE bottle with silica gel desiccants and child resistant closure with induction seal liner.

**Holder of Certificate of Registration**

Ranbaxy Pharmaceuticals (Pty) Ltd

14 Lautre Road, Stormill Ext.1

Roodepoort, 1724

South Africa

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