

Patient Information Leaflet

SCHEDULING STATUS:

S3

ZITAGLUC 25 film coated tablets

ZITAGLUC 50 film coated tablets

ZITAGLUC 100 film coated tablets

(Sitagliptin)

Sugar Free

Read all of this leaflet carefully before you start taking ZITAGLUC

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

1. What ZITAGLUC is and what it is used for

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

Type 2 diabetes is also called non-insulin-dependent diabetes mellitus, or NIDDM.

ZITAGLUC helps to improve the levels of insulin after a meal.

Your doctor has prescribed sitagliptin to help lower your blood sugar, which is too high because of your type 2 diabetes. Sitagliptin can be used alone or in combination with certain other medicines (metformin or a PPAR γ agonist e.g. thiazolidinedione) that lower blood sugar levels, along with a recommended 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 the blood. This can lead to serious medical problems like heart disease, kidney disease, blindness, and amputation.

2. What you need to know before you take ZITAGLUC

Do not take ZITAGLUC if:

- if you are hypersensitive (allergic) to sitagliptin or other member of gliptins or any of the other ingredients of ZITAGLUC tablets (listed in section 6.1).

Warnings and precautions

Hypersensitivity Reactions:

There have been post-marketing reports of serious hypersensitivity reactions in patients treated with sitagliptin. These reactions include anaphylaxis, angioedema and exfoliative skin conditions including Stevens-Johnson syndrome. Onset of these reactions have been reported within the first 3 months after initiation of treatment with sitagliptin, with some reports reported after the first dose. If a hypersensitivity reaction is suspected, discontinue ZITAGLUC immediately, and institute an alternative class of medicines for treatment for diabetes (see section 4.3 and 4.8).

Take special care with ZITAGLUC:

- if you have inflammation of the pancreas, having symptoms such as severe upper stomach pain, often with nausea and vomiting (Pancreatitis) have been reported in patients receiving sitagliptin. Pancreatitis can be a serious, potentially life threatening medical condition. Stop taking sitagliptin and call your doctor if you experience frequent or persistent stomach pain, with or without vomiting, because you could have pancreatitis.
- if you have allergic reactions (symptoms may include such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing).
- if you have Type 1 diabetes characterized by not enough insulin produced by the body (symptoms include excessive thirst, increased appetite with weight loss, feeling tired, drowsy, weak, depressed, irritable and generally unwell, and passing large amounts of urine).

- Diabetic ketoacidosis (if you have symptoms such as loss of appetite, unexplained weight loss, nausea, vomiting, stomach pain, difficulty breathing, slow heart-beat, unusual muscle pain or feeling weak, tired or uncomfortable).
- if you have any past or present kidney problems.
- if you encounter blistering of the skin it may be a sign for a condition called bullous pemphigoid.

Sitagliptin is unlikely to cause low blood sugar because it does not work when your blood sugar is low. However, when this medicine 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

No reported data available on the use of sitagliptin in patients younger than 18 years of age. Do not give ZITAGLUC to children below 18 years.

Other medicines and ZITAGLUC

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

In particular, tell your doctor if you are taking digoxin (a medicine used to treat irregular heart beat and other heart problems). The level of digoxin in your blood may need to be checked if taking with ZITAGLUC.

If you are taking potent CYP3A4 inhibitors (i.e. ketoconazole, itraconazole [used for fungal infections] ritonavir [medicines that help control HIV infection], clarithromycin [(medicines for bacterial infections)], probenecid (used to treat gout).

If you are taking diabetes medicine (i.e. metformin).

If you are taking an immune suppressor (e.g. ciclosporin).

ZITAGLUC with food, drink and alcohol

ZITAGLUC should be taken by mouth, swallowed with liquid and may 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.

Pregnancy

Sitagliptin is not recommended during the pregnancy

Breastfeeding

It is not known if sitagliptin passes into breast milk. You should not take sitagliptin if you are breast-feeding or plan to breast-feed

Driving and using machines

There is no information to suggest that sitagliptin affects your 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 ZITAGLUC in combination with medicines called sulphonylureas or with insulin can cause hypoglycaemia (low blood sugar levels), which may affect your ability to drive and use machines or work without safe foothold.

3. How to take ZITAGLUC

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

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

The recommended dose to take is:

One 100 mg tablet, once a day by mouth, with or without food.

If you have impression that the effect of ZITAGLUC is too strong or too weak, talk to you doctor or pharmacist.

If you have kidney problem, your doctor may prescribe lower dose.

Your doctor may prescribe ZITAGLUC along with certain other medicines (metformin or a PPARy agonist e.g. thiazolidinedione) that may lower blood sugar levels.

Diet and exercise can help your body use its blood sugar better. It is important to stay on your doctor recommended diet, exercise and weight loss program while taking ZITAGLUC

If you take more ZITAGLUC 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 forget to take ZITAGLUC

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 ZITAGLUC

Continue taking ZITAGLUC 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 ZITAGLUC 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 you have questions about how long to take ZITAGLUC, talk to your doctor.

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

4. Possible side effects

ZITAGLUC can have side effects.

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

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

- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing, as these may be signs of a serious allergic (anaphylactic) reaction,
- a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome),
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (angioedema)

If you have them, you may have had a serious reaction to ZITAGLUC. 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:

- An acute or chronic autoimmune skin disease, involving the formation of blisters, more appropriately known as bullae, at the space between the skin layers (bullous pemphigoid).
- inflammation of the pancreas, symptoms include severe upper stomach pain, often with nausea and vomiting (pancreatitis)
- kidney problems (sometimes requiring dialysis)

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Low blood sugar
- Headache
- Nausea
- Stomach discomfort or fullness, relieved by belching or passing wind (flatulence)

Less frequent side effects:

- Low blood platelet count having symptoms bleeding or bruising more easily than normal (thrombocytopenia)
- Sleepiness or drowsiness (somnolence)
- Sensation of unsteadiness (dizziness)
- Loose stool (diarrhoea)
- Upper abdominal pain
- Constipation

- Itching

Frequency *unknown*:

- If you have symptoms dry cough, shortness of breath, fatigue or inability to exercise (interstitial lung disease)
- Upper respiratory tract infections with symptoms such as sore throat and stuffy nose (nasopharyngitis)
- Vomiting (being sick)
- Inflammation of the blood vessels in the skin (cutaneous vasculitis)
- Aching muscles, muscle tenderness or weakness, not caused by exercise (myalgia)
- Painful, swollen joints, decreased range of motion stiffness (arthralgia/ arthropathy)
- Painful joint disease, most commonly affecting the hips, knees and spine (osteoarthritis), pain in extremity
- flu-like symptoms, such as high temperature, sore throat, runny nose, cough and chills
- dry mouth
- rash, hives

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. 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 ZITAGLUC.

5. How to store ZITAGLUC

- 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 from the blister only immediately prior to intake.
- Do not take ZITAGLUC 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 contains

The active substance is sitagliptin.

ZITAGLUC 25 :

Each film coated tablet contains 25 mg sitagliptin.

ZITAGLUC 50 :

Each film coated tablet contains 50 mg sitagliptin.

ZITAGLUC 100 :

Each film coated tablet contains 100 mg sitagliptin.

The other ingredients are: Calcium hydrogen phosphate, crospovidone (type-a), glycerol dibehenate, hydrogenated castor oil, isopropyl alcohol magnesium stearate and methylene chloride.

Film coating

Opadry Pink 02F540038 (25 mg)

HPMC 2910/Hypromellose, iron oxide yellow, iron oxide red, macrogol/peg (MW 6000), talc, titanium dioxide

Opadry Beige 02F570009 (50 mg)

HPMC 2910/Hypromellose, iron oxide yellow, iron oxide red, macrogol/peg (MW 6000), talc, titanium dioxide

Opadry Beige 02F570006 (100 mg)

HPMC 2910/Hypromellose, iron oxide yellow, iron oxide red, macrogol/peg (MW 6000), talc, titanium dioxide

What ZITAGLUC looks like and contents of the pack

ZITAGLUC 25

Light pink colour, round film coated tablets debossed with **F1** on one side and plain on the other side.

ZITAGLUC 50

Light beige colour, round film coated tablets debossed with **F2** on one side and plain on the other side

ZITAGLUC 100

Beige colour, round film coated tablets debossed with **F3** on one side and plain on the other side.

HDPE Bottle Pack:

The product can be supplied in pack sizes of 90's comprising of an HDPE bottle with silica gel desiccants and child resistant closure with induction seal liner.

Blister packs:

The product can be supplied in blister packs of 3 x 10's comprising of a desiccant embedded cold form laminate with the oriented polyamide, aluminium foil, polyethylene, desiccant and HDPE coating with a backing of lidding laminate comprising of aluminum foil and heat seal extrusion coating.

Holder of Certificate of Registration

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