PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S3

GLUSITA 25 mg (film-coated tablet)

GLUSITA 50 mg (film-coated tablet)

GLUSITA 100 mg (film-coated tablet)

Active ingredient: Sitagliptin phosphate monohydrate.

GLUSITA is sugar free.

Read all of this leaflet carefully before you start taking GLUSITA

- 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.
- GLUSITA 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 GLUSITA is and what it is used for

GLUSITA 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 adult patients with type 2 diabetes mellitus.

This medicine helps to increase the levels of insulin produced after a meal and decreases the amount of sugar made by the body. Along with diet and exercise, this medicine helps lower your blood sugar which is too high because of your type 2 diabetes.

This medicine can be used alone or in combination with certain other medicines (insulin, metformin, sulphonylureas, or glitazones) that lower blood sugar, which you may already be taking for your diabetes together with a food and exercise plan.

2. What you need to know before you take GLUSITA

Do not take GLUSITA if:

- You are hypersensitive (allergic) to sitagliptin or other gliptins (DPP-4), or any of the other ingredients of GLUSITA (listed in section 6).

Warnings and precautions

Tell your doctor or health care provider before taking GLUSITA:

- If you have type 1 diabetes. GLUSITA should not be used in patients with type 1 diabetes and must not be used for the treatment of diabetic ketoacidosis (a complication of diabetes with high blood sugar, rapid weight loss, nausea or vomiting).
- If you have or have had a disease of the pancreas (such as pancreatitis). Cases of inflammation of the pancreas (pancreatitis) have been reported in patients receiving GLUSITA. If you have or have had gallstones, alcohol dependence or very high levels of triglycerides (a form of fat) in your blood you may have an increased chance of getting pancreatitis (see section 4).

- This medicine 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.
- If you encounter blistering of the skin it may be a sign for a condition called bullous pemphigoid. Your doctor may ask you to stop GLUSITA.
- If you have kidney problems or reduced kidney function. During treatment with GLUSITA, 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.
- If you have or have had an allergic reaction to sitagliptin or GLUSITA (see section 4).

Children and adolescents

Children and adolescents below 18 years should not use GLUSITA. It is not known if this medicine is safe and effective when used in children and adolescents under 18 years of age.

Other medicines and GLUSITA

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 taken with GLUSITA.

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 health care provider for advice before taking GLUSITA. You should not take GLUSITA during pregnancy.

It is not known if GLUSITA passes into breast milk. You should not take GLUSITA if you are breastfeeding or plan to breastfeed.

Driving and using machines

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

Taking GLUSITA 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.

Important information about some of the ingredients of GLUSITA:

GLUSITA contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take GLUSITA

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

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

The usual recommended dose is one 100 mg film-coated tablet once a day with or without food and drink.

If you have kidney problems, your doctor may prescribe lower doses (such as 25 mg or 50 mg).

Your doctor may prescribe GLUSITA alone or with certain other medicines that lower blood sugar. Diet and exercise can help your body use its blood sugar better. It is important to stay on the diet and exercise recommended by your doctor.

Your doctor will tell you how long your treatment with GLUSITA will last. Do not stop your treatment early. If you have the impression that the effect of GLUSITA is too strong or too weak, tell your doctor or pharmacist.

If you take more GLUSITA than you should

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

If you forget to use GLUSITA

If you miss a dose, take it as soon as you remember. If you do not remember until it is time for your next dose, skip the missed dose and go back to your regular schedule. Do not take a double dose of GLUSITA.

If you stop using GLUSITA

Continue to take GLUSITA 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 GLUSITA, your blood sugar may rise again.

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

4. Possible side effects

GLUSITA can cause side effects.

Not all side effects reported for GLUSITA are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking GLUSITA, please consult your healthcare provider for advice.

If any of the following happens, stop taking GLUSITA 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). Pancreatitis can be a serious, potentially life-threatening medical condition. Stop taking GLUSITA and call your doctor right away if you experience these symptoms.
- 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 very serious side effects. 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:

- Kidney problems (sometimes requiring dialysis) while taking GLUSITA.

This is a serious side effect. You may need urgent medical attention.

Tell your doctor if you notice any of the following;

Frequent side effects:

- Low blood sugar
- Nausea
- Flatulence
- Headache

- Painful joint disease; most frequently affecting the hips, knees and spine
- Arm or leg pain
- Foot swelling
- Upper respiratory infection
- Stuffy or runny nose and sore throat

Less frequent side effects:

Tell your doctor if you notice my al the following:

- Drowsiness
- Dizziness
- Constipation
- Abdominal pain
- Diarrhoea
- Vomiting
- Redness of the skin (rash) or itching.
- Thrombocytopenia (reduced number of platelets)
- Decreased blood glucose levels
- Severe inflammation of the skin including Stevens-Johnson syndrome a rare, serious disorder of the skin and mucous membranes that starts with flu-like symptoms, followed by a painful rash that spreads and blisters.
- Bullous pemphigoid, a rare skin condition causing large, fluid-filled blisters.

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 **"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 GLUSITA.

Suspected adverse reactions can also be reported directly to the company via Patientsafety.sacg@novartis.com.

5. How to store GLUSITA

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store below 30 °C.

Do not use this medicine after the expiry date stated on the blister and the carton.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What GLUSITA contains

- The active substance is Sitagliptin (as phosphate monohydrate). One tablet contains 25 mg, 50 mg or 100 mg respectively.
- The other ingredients are: In the tablet core: Calcium hydrogen phosphate anhydrous, microcrystalline cellulose, croscarmellose sodium, low-substituted hydroxypropyl cellulose, colloidal silicon dioxide, magnesium stearate, sodium stearyl fumarate
- In addition, the film coating contains: Hydroxypropylmethyl cellulose viscosity grade 6 mPa s (2 %. 20 °C), hydroxypropylcellulose. viscosity grade 300 – 600 mPa s (10 %. 25 °C), polyethylene glycol 6000, titanium dioxide (E 171), ferric oxide yellow (E 172), ferric oxide red (E 172), ferric oxide black (E 172) (100 mg only), talc.

What GLUSITA looks like and contents of the pack

GLUSITA 25 mg (film-coated tablet).

Dark pink, round, biconvex film coated tablet debossed with “SN” on one side and “25” on the other side.

GLUSITA 50 mg (film-coated tablet).

Pink, round, biconvex film coated tablet debossed with “SN” on one side and “50” on the other side.

GLUSITA 100 mg (film-coated tablet).

Brown, round, biconvex film coated tablet debossed with “SN” on one side and “100” on the other side.

GLUSITA 25 mg, 50 mg or 100 mg film coated tablets are packed in Al/Al blisters and PVDC blisters, in packs of 28, 30, 56 and 60 tablets with blisters of 7 or 10 tablets.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

Magwa Crescent West

Waterfall City

Jukskei View

Midrand

2090

This leaflet was last revised in

TBA

Registration number

To be allocated by Council upon registration.

Access to the corresponding Professional Information

TBA

[1]Company Reg. No.: 1990/001979/07