PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

GLUSITA PLUS 50 mg/500 mg (film-coated tablets)

GLUSITA PLUS 50 mg/850 mg (film-coated tablets)

GLUSITA PLUS 50 mg/1000 mg (film-coated tablets)

Active ingredients: Sitagliptin phosphate monohydrate and metformin hydrochloride.

GLUSITA PLUS is sugar free.

Read all of this leaflet carefully before you start taking GLUSITA 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.
- GLUSITA PLUS has been prescribed for you personally and you should not share your medicine with other people. It may harm then, even if their symptoms are the same as yours.

What is in this leaflet

1. What GLUSITA PLUS is and what it is used for

GLUSITA PLUS contains two active substances sitagliptin and metformin.

• Sitagliptin belongs to a class of medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors)

• Metformin belongs to a class of medicines called biguanides.

They work together to control blood sugar levels in adult patients with a form of diabetes called 'type 2 diabetes mellitus'. GLUSITA PLUS helps to increase the levels of insulin produced after a meal and lowers the amount of sugar made by your body.

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

2. What you need to know before you take GLUSITA PLUS

Do not take GLUSITA PLUS if:

- You are hypersensitive (allergic) to sitagliptin or metformin or any of the other ingredients of GLUSITA PLUS (listed in section 6).
- You have severely reduced kidney function.
- 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.
- You have a severe infection or are dehydrated.

- You have recently had a heart attack or have severe circulatory problems, such as ‘shock’ or breathing difficulties.
- You have liver problems.
- You drink alcohol to excess (either every day or only from time to time).
- You are pregnant or plan to become pregnant or are breast-feeding.
- You are going to have an X-ray where you will be injected with a dye. You will need to stop taking GLUSITA PLUS at the time of the X-ray and for 2 or more days after as directed by your doctor, depending on how your kidneys are working.

Do not take GLUSITA PLUS if any of the above apply to you and talk with your doctor about other ways of managing your diabetes.
If you are not sure, talk to your doctor, pharmacist or nurse before taking GLUSITA PLUS.

Warnings and precautions

Tell your doctor or health care provider before taking GLUSITA PLUS:

- If you have type 1 diabetes. GLUSITA PLUS should not be used in patients with type 1 diabetes and must not be used for the treatment of diabetic ketoacidosis (a condition in which substances called ‘ketone bodies’ accumulate in the blood).
- 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 PLUS. 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)
- If you experience any of the following symptoms that are associated with lactic acidosis, a very rare, but very serious side effect that may be caused by GLUSITA PLUS, particularly if your kidneys are not working properly:
    - 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

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). Lactic acidosis is a medical emergency that may lead to coma and must be treated in a hospital.

- If you have kidney problems or reduced kidney function. During treatment with GLUSITA 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.
- If you are taking a sulphonylurea or insulin (diabetes medicines), together with GLUSITA PLUS, as you may experience low blood sugar levels (hypoglycaemia). Your doctor may reduce the dose of your sulphonylurea or insulin
- If you have or have had an allergic reaction to sitagliptin, metformin, or GLUSITA PLUS (see section 4)
- 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 PLUS.
- If you need to have major surgery, you must stop taking GLUSITA PLUS during and for some time after the procedure. Your doctor will decide when you must stop and when to restart your treatment with GLUSITA PLUS.
- If you are going to have an X-ray where you will be injected with a dye. You will need to stop taking GLUSITA PLUS at the time of the X-ray and for 2 or more days after as directed by your doctor, depending on how your kidneys are working.

Children and adolescents

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

Other medicines and GLUSITA PLUS

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

GLUSITA PLUS may affect how well other medicines work and some medicines can affect how well GLUSITA PLUS works.
You may need more frequent blood glucose and kidney function tests, or your doctor may need to adjust the dosage of GLUSITA PLUS.

If you need to have an injection of a contrast medium that contains iodine into your bloodstream, for example, in the context of an X-ray or scan, you must stop taking GLUSITA PLUS before or at the time of the injection. Your doctor will decide when you must stop and when to restart your treatment with GLUSITA PLUS.

It is especially important to mention if you are taking the following:

- 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)
- 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-2-agonists)

- Iodinated contrast materials.
- Alcohol-containing medicines.
- Certain medicines used to treat stomach problems such as cimetidine.
- Ranolazine, a medicine used to treat angina
- Dolutegravir, a medicine used to treat HIV infection
- Vandetanib, a medicine used to treat a specific type of thyroid cancer (medullary thyroid cancer).
- Digoxin (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 PLUS.

GLUSITA PLUS with alcohol

The use of alcohol whilst taking GLUSITA PLUS is not recommended since this may increase the risk of lactic acidosis, particularly in cases of fasting, malnutrition or liver problems (see section “Warnings and precautions”).

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 this medicine.

You should not take GLUSITA PLUS during pregnancy or if you are breast-feeding.

Driving and using machines

GLUSITA 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 GLUSITA PLUS 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 PLUS:

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

3. How to take GLUSITA PLUS

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

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

The starting dose of GLUSITA PLUS should be based on your current regimen.

The usual dose is one tablet twice daily 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.

GLUSITA PLUS alone is unlikely to cause abnormally low blood sugar (hypoglycaemia). When GLUSITA PLUS is used with a sulphonylurea medicine (a medicine to control blood sugar levels), low blood sugar can occur, and your doctor may reduce the dose of your sulphonylurea.

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

If you take more GLUSITA PLUS than you should

If you take more than the prescribed dosage of GLUSITA PLUS you may experience symptoms of lactic acidosis such as feeling cold or uncomfortable, severe nausea or vomiting, stomach ache, unexplained weight loss, muscular cramps, or rapid breathing (see section “Warnings and precautions”).

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 PLUS

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 PLUS.

If you stop using GLUSITA PLUS

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

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

4. Possible side effects

GLUSITA PLUS can cause side effects.

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

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

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

- Feeling sick (nausea) or being sick (vomiting), abdominal pain, muscular cramps, unexplained weight loss, rapid breathing and feeling cold or uncomfortable. Metformin, one of the medicines in GLUSITA PLUS may cause a very rare, but very serious side effect called lactic acidosis (too much lactic acid in your blood) (see section “Warnings and precautions”). This is more common in people whose kidneys are not working properly. Lactic acidosis is a medical emergency that may lead to coma, can cause death, and must be treated in the hospital. Stop taking GLUSITA PLUS if you get any of the above symptoms of lactic acidosis and see your doctor immediately.
- 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 GLUSITA PLUS and call your doctor right away. Your doctor may prescribe a medicine to treat your allergic reaction and a different medicine for your diabetes.
- 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 PLUS and call your doctor right away if you experience these symptoms.

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) or hepatitis (a problem with your liver) while taking GLUSITA PLUS.

These are 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
- Nausea
- Vomiting
- Flatulence (excessive wind in the stomach or bowel)
- Constipation
- Upper abdominal pain
- Diarrhoea
- Loss of appetite
- 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
- A metallic taste

Less frequent side effects:

Tell your doctor if you notice my al the following:

- Drowsiness,
- Dizziness
- Decreased vitamin B_{12} levels
- Redness of the skin (rash) or itching.
- Thrombocytopenia (reduced number of platelets)

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 PLUS.

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

5. How to store GLUSITA PLUS

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store below 30 °C.

Do not use GLUSITA PLUS 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 PLUS contains

- The active substance is Sitagliptin (as phosphate monohydrate) and metformin hydrochloride. One tablet contains 50 mg / 500 mg; 50 mg/850 mg or 50 mg/1000 mg respectively.

- The other ingredients are: In the tablet core: povidone K30, sodium lauryl sulfate, microcrystalline cellulose, croscarmellose sodium, sodium stearyl fumarate.

- In addition, the film-coating contains: HPMC (hypromellose type 2910), hydroxypropyl cellulose, triethyl citrate, titanium dioxide, E172, talc, ferric oxide red E171, ferric oxide yellow E171 (50 mg/850 mg & 50 mg/1000 mg strengths only).

What GLUSITA PLUS looks like and contents of the pack

GLUSITA PLUS 50 mg/500 mg (film-coated tablet) is a pink oval biconvex film-coated tablet debossed with “SM01” on one side.
GLUSITA PLUS 50 mg/850 mg (film-coated tablet) is a light orange oval biconvex film-coated tablet debossed with “SM02” on one side
GLUSITA PLUS 50 mg/1 000 mg (film-coated tablet) is a light red oval biconvex film-coated tablet debossed with “SM03” on one side.

GLUSITA PLUS film-coated tablets are packed in Al / Al blisters and PVDC blisters, in packs of 28 and 56 tablets with blisters of 7 tablets.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

Waterfall 5-lr

Magwa Crescent West

Waterfall City

Jukskei View

2090

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GLUSITA PLUS 50 mg/500 mg: 55/21.2/0676

GLUSITA PLUS 50 mg/850 mg: 55/21.2/0677

GLUSITA PLUS 50 mg/1 000 mg: 55/21.2/0678

Access to the corresponding Professional Information

Not applicable.

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