SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Glysit Met 5/500 mg film coated Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film coated tablet contains:

Dapagliflozin ……5 mg

Metformin……500 mg

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film coated Tablet. Orange, capsule shaped film coated tablet embossed COSMOS on one side and plain on other side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Type 2 diabetes mellitus: It is indicated in adults for the treatment of insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise.

4.2 Posology and method of administration

The recommended dose is one or two tablets once daily.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings and precautions for use

Dapagliflozin

Renal impairment

The glycaemic efficacy of Dapagliflozin is dependent on renal function; reduced efficacy in moderate renal impairment, likely absent in severe renal impairment.

Hepatic impairment

There is limited experience in clinical studies in patients with hepatic impairment.

Use in patients at risk for volume depletion and/or hypotension

Dapagliflozin increases diuresis which may lead to a modest decrease in blood pressure.

Diabetic ketoacidosis

SGLT2 inhibitors should be used with caution in patients with increased risk of DKA.

Metformin

Lactic acidosis

Lactic acidosis is a rare but serious metabolic complication most often occurring at acute worsening of renal function or cardiorespiratory illness/sepsis. In case of dehydration, metformin should be temporarily discontinued. Risk factors include excessive alcohol intake, hepatic insufficiency, inadequately controlled diabetes, ketosis, prolonged fasting, and hypoxia-associated conditions.

Renal function

GFR should be assessed before treatment and regularly thereafter. Metformin is contraindicated in patients with GFR<30 mL/min.

Cardiac function

Patients with heart failure are at increased risk of hypoxia and renal insufficiency; contraindicated in acute/unstable heart failure.

Administration of iodinated contrast agents

Metformin must be discontinued prior to or at the time of imaging and not restarted until at least 48 hours after, provided renal function is stable.

Surgery

Metformin must be discontinued at time of surgery under general/spinal/epidural anaesthesia; restart no earlier than 48 hours after, provided renal function is stable.

4.5 Interaction with other medicinal products and other forms of interaction

Dapagliflozin

Diuretics: May add to the diuretic effect of thiazide/loop diuretics, increasing risk of dehydration and hypotension. Insulin/insulin secretagogues: Lower doses may be needed to reduce hypoglycaemia risk.

Metformin

Alcohol: Increased risk of lactic acidosis. Iodinated contrast agents: discontinue as above. NSAIDs, ACE inhibitors, angiotensin II receptor antagonists, and loop diuretics: close monitoring of renal function necessary. OCT1/OCT2 inhibitors/inducers (verapamil, rifampicin, cimetidine, dolutegravir, ranolazine, trimethoprim, vandetanib, isavuconazole, crizotinib, olaparib) may alter metformin efficacy/elimination.

4.6 Fertility, pregnancy and lactation

Dapagliflozin

No data in pregnant women; not recommended in 2nd/3rd trimesters; discontinue when pregnancy detected. Should not be used while breast-feeding.

Metformin

Large datasets indicate no increased risk of congenital abnormalities or feto/neonatal toxicity. Can be considered during pregnancy if clinically needed. Excreted into breast milk; breast-feeding not recommended due to limited data. Fertility unaffected in rats at doses up to 600 mg/kg/day.

4.7 Effects on ability to drive and use machines

Glysit Met has no or negligible influence on ability to drive and use machines. Patients should be alerted to the risk of hypoglycaemia.

4.8 Undesirable effects

Dapagliflozin

Very common: Hypoglycaemia (with SU/insulin). Common: Genital infections, UTI, dizziness, rash, back pain. Uncommon: Fungal infection, volume

depletion, thirst, constipation, dry mouth. Very rare: Necrotising fasciitis of the perineum, angioedema. Rare: Diabetic ketoacidosis.

Metformin

Common: Vitamin B12 decrease/deficiency, taste disturbance. Very common: Gastrointestinal disorders (nausea, vomiting, diarrhoea, abdominal pain, loss of appetite). Very rare: Lactic acidosis; liver function test abnormalities/hepatitis; skin reactions (erythema, pruritus, urticaria).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org'

4.9 Overdose

Dapagliflozin

No toxicity at single doses up to 500 mg (50x max recommended dose); no clinically meaningful effect on QTc.

Metformin

Hypoglycaemia not seen with doses up to 85g, though lactic acidosis has occurred; treated as medical emergency, haemodialysis most effective removal method.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Dapagliflozin

SGLT2 inhibitor reducing renal glucose reabsorption, increasing urinary glucose excretion independent of insulin secretion/action.

Metformin

Biguanide lowering basal/postprandial glucose via reduced hepatic glucose production, increased insulin sensitivity, and delayed intestinal glucose absorption; favourable lipid effects.

5.2 Pharmacokinetic properties

Dapagliflozin

Cmax at ~2h, absolute bioavailability 78%; ~91% protein bound; metabolised via UGT1A9; terminal half-life 12.9 hours.

Metformin

Cmax at ~2.5h, absolute bioavailability 50-60%; negligible protein binding; renal clearance >400 mL/min; terminal half-life ~6.5 hours; excreted unchanged in urine.

5.3 Preclinical safety data

Dapagliflozin

No special hazard based on conventional studies; renal pelvic/tubular dilatations observed in juvenile/pregnant rat studies.

Metformin

No special hazard based on conventional studies of safety, pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential and reproductive toxicity.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

- Microcrystalline cellulose 101 USP
- Sodium lauryl sulphate BP
- Povidone K 30 BP
- Partially pregelatinized starch 1500 BP
- Sodium starch glycolate BP
- Magnesium stearate BP
- Aerosil BP
- Croscarmellose sodium BP

Film coating:

- Hypromellose BP
- Propylene glycol BP
- Purified Talc BP

- Titanium dioxide BP
- Sunset aluminium lake colour

6.2 Incompatibilities

Not Applicable.

6.3 Shelf life

2 Years.

6.4 Special precautions for storage

Store in a dry place below 30°C. Protect from light. Keep all medicines out of the reach of children.

6.5 Nature and contents of container

Aluminium/Aluminium blister pack; 30 tablets packed in blisters in cartons with literature insert.

6.6 Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

H2022/CTD10276/23105

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10. DATE OF REVISION OF THE TEXT

22-08-2026