Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product

Glucoset 20 mg Film-coated Tablets.

2. Qualitative and quantitative composition

Each film-coated tablet contains: Teneligliptin 20 mg

For a full list of excipients, see Section 6.1.

3. Pharmaceutical form

Film-coated tablet.

4. Clinical particulars

4.1 Therapeutic Indications

Glucoset is indicated for the treatment of Type 2 Diabetes Mellitus in adults as an adjunct to diet and exercise to improve glycaemic control, either as monotherapy or in combination with other antidiabetic agents.

4.2 Posology and Method of Administration

Adults

The recommended dose is 20 mg once daily.

The dose may be increased to 40 mg once daily under medical supervision if glycaemic control is inadequate.

Elderly Patients

No dosage adjustment is generally required; caution should be exercised in elderly patients.

Renal Impairment

Use with caution. Dose adjustment should be considered according to clinical condition and local treatment guidelines.

Hepatic Impairment

Administer with caution in patients with hepatic impairment.

Method of Administration

For oral administration.

Tablets should be swallowed whole with water and may be taken with or without food.

4.3 Contraindications

- Hypersensitivity to teneligliptin or any excipient.
- Type 1 diabetes mellitus.
- Diabetic ketoacidosis.

- Diabetic coma or pre-coma.
- Severe infections requiring insulin therapy.
- Major surgery or severe trauma requiring insulin therapy.

4.4 Special Warnings and Precautions for Use

- Use with caution in patients with liver impairment.
- Use with caution in patients with heart failure or cardiovascular disease.
- Hypoglycaemia may occur when used with insulin or sulphonylureas.
- Patients should be monitored regularly for glycaemic control.
- Caution is advised in patients with electrolyte abnormalities or cardiac disorders.

4.5 Interaction with Other Medicinal Products and other forms of interaction

Caution should be exercised when administered with:

- Sulphonylureas and insulin
- Beta-blockers
- Monoamine oxidase inhibitors (MAOIs)
- Corticosteroids
- Thyroid hormones
- Other medicines affecting glucose metabolism

4.6 Pregnancy and Lactation

Pregnancy

Use during pregnancy is not recommended unless clearly necessary.

Breastfeeding

Use during breastfeeding is not recommended.

Fertility

No adequate human fertility data are available.

4.7 Effects on Ability to Drive and Use Machines

Glucoset has no or negligible influence on the ability to drive and use machines. Patients who experience dizziness or hypoglycaemia should avoid driving or operating machinery.

4.8 Undesirable Effects

Common adverse reactions include:

- Hypoglycaemia
- Constipation
- Nausea
- Abdominal discomfort
- Rash
- Gastrointestinal disturbances
- Proteinuria

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are requested to report any suspected adverse reactions to the Pharmacy and Poisons Board (PPB) through the Pharmacovigilance Electronic Reporting System (PvERS) at **https://pv.pharmacyboardkenya.org/** or by using the approved PPB ADR reporting forms

4.9 Overdose

In the event of overdose, supportive treatment should be initiated and clinical monitoring undertaken, including cardiovascular monitoring and ECG assessment where appropriate.

5. Pharmacological properties

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: DPP-4 Inhibitors

Glucoset 20 mg Tablet exerts its actions in patients with type 2 diabetes by slowing the inactivation of incretin hormones. Concentrations of the active intact hormones are increased by teneligliptin, thereby increasing and prolonging the action of these hormones. Incretin hormones, including glucagon-like peptide-1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP), are released by the intestine throughout the day, and levels are increased in response to a meal. These hormones are rapidly inactivated by the enzyme, DPP-4. The incretins are part of an endogenous system involved in the physiologic regulation of glucose homeostasis. When blood glucose concentrations are normal or elevated, GLP-1 and GIP increase insulin synthesis and release from pancreatic beta cells by intracellular signaling pathways involving cyclic AMP. GLP-1 also lowers glucagon secretion from pancreatic alpha cells, leading to reduced hepatic glucose production. By increasing and prolonging active incretin levels, teneligliptin increases insulin release and decreases glucagon levels in the circulation in a glucose-dependent manner.

5.2 Pharmacokinetic Properties

After oral administration of a single 20 mg and 40 mg dose to healthy subjects, teneligliptin was rapidly absorbed, with peak plasma concentrations (mean T max) occurring at 1.8 hours and 1 hour post dose. Plasma AUC of teneligliptin increased in a dose-proportional manner. Following a single oral 20 mg and 40 mg dose to healthy volunteers, mean plasma AUC of teneligliptin was 2028.9 and 3705.1 ng hr/ml, Cmax was 187.2 and 382.4 ng/ml, and apparent terminal half-life (t1/2) was 24.2 and 20.8 hours. Plasma AUC of teneligliptin increased following 20 mg doses at steady-state compared to the first dose. Co-administration with food reduces the Cmax by 20%, increases the Tmax from 1.1 to 2.6 hours but does not affect the AUC of teneligliptin as compared to that in the fasting state. The plasma protein binding rate is 77.6 – 82.2%. Following a 20 mg single oral dose of [14C] teneligliptin, 5 metabolites M1, M2, M3, M4 and M5 were observed. In vitro studies indicated that CYP3A4 and flavin-containing monooxygenase (FMO1 and FMO3) are involved in the metabolism of teneligliptin. Teneligliptin does not inhibit CYP1A2, CYP2A6, CYP2B6, CYP2C8, CYP2C8/9, CYP2C19, CYP2E1, is a weak inhibitor of CYP2D6, CYP3A4, and FMO does not induce CYP3A4 and CYP1A2. Following a 20 mg single oral dose of teneligliptin, 45.4% of administered radioactivity was excreted in urine and 46.5% in faeces till 216 hours after dose. The cumulative urinary excretion rates for up to 120 hours for un-metabolized, M1, M2, and M3 were 14.8%, 17.7%, 1.4% and 1.9% respectively while the cumulative faecal excretion rates for un-metabolized, M1, M3, M4 and M5 were 26.1%, 4.0%, 1.6%, 0.3% and 1.3% respectively.

5.3 Preclinical Safety Data

Non-clinical studies revealed no special hazards based on conventional safety pharmacology and toxicity studies.

6. Pharmaceutical particulars

6.1 List of Excipients

FLOCEL 101 USP
Hydroxypropyl cellulose Partially
pregelatinized starch Yellow iron oxide
Croscarmellose sodium Dried Aerosil
Magnesium stearate Sodium starch
glycollate Opadry II Yellow

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

24 months.

6.4 Special Precautions for Storage

Store below 30°C.

Protect from light and moisture.

6.5 Nature and Contents of Container

Aluminium/Aluminium blister packs.

Pack size(s): 30 Tablets.

6.6 Special precautions for disposal and other handling

No special requirements.

7. Marketing Authorization Holder

Cosmos Limited, P.o Box 0041433 Nairobi Kenya

8. Marketing Authorization Number

H2022/CTD8103/17833

9. Date of first authorization/renewal of the authorization

August 2026

10. Date of revision of the text

August, 2026