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VERSION NO.: 012	**PACKAGING MATERIAL SPECIFICATION**	SUPERSEDES INS057/04.18/011
GLUCOMET TABLETS INFORMATION LITERATURE INSERT		

CAUTION
Do not make any changes without authorization

INSERT SAMPLE
(Ref. No. B2121500/22.01)

Glucomet® (Tablets)

Metformin Hydrochloride
Biguanide Antidiabetic

GLUCOMET® 500MG FILM COATED TABLETS
GLUCOMET® 850MG FILM COATED TABLETS

21500
Ref. No: B2121500/22.01

PRESENTATION:
Glucomet® Tablets 500mg: White, circular, biconvex, film coated tablet embossed 'GLUCOMET' on one side and '500' on the other side. Each film coated tablet contains: Metformin Hydrochloride 500mg.
Glucomet® Tablets 850mg: White, oblong-shaped, biconvex, film coated tablet embossed 'COSMOS' on one side and a breakline on the other side. Each film coated tablet contains: Metformin Hydrochloride 850mg.

CLINICAL PHARMACOLOGY:
Metformin Hydrochloride is a biguanide antidiabetic. Glucomet® is given orally for the treatment of type 2 diabetes mellitus. Glucomet® does not stimulate insulin release and requires that some insulin be present in order to exert its antidiabetic effect. Possible mechanisms of action include delay in the absorption of glucose from the gastro-intestinal tract, an increase in insulin sensitivity and glucose uptake into cells, and inhibition of hepatic gluconeogenesis. Glucomet® does not produce hypoglycaemia in either normal subjects or patients with type 2 diabetes and does not cause hyperinsulinemia.

Pharmacokinetics:
Metformin Hydrochloride is slowly and incompletely absorbed from the gastro-intestinal tract; the absolute bioavailability of a single 500mg dose is reported to be about 50 to 60%, although this is reduced somewhat if taken with food. Following absorption plasma protein binding is negligible, and it is excreted unchanged in the urine. The plasma elimination half-life is reported to range from about 2 to 6 hours after oral administration.

USES:
Glucomet® as monotherapy is indicated as an adjunct to diet and exercise in the management of type 2 diabetes. Glucomet® may be used in combination with sulphonylureas, thiazolidinediones and insulin to improve glycaemic control in adults.

DOSAGE AND ADMINISTRATION:
Children 10 years and over and adolescents
The usual starting dose is 500 or 850 mg once a day. The maximum daily dose is 2000mg taken as 2 or 3 divided doses.
Treatment of children between 10 and 12 years of age is only recommended on specific advice from your doctor, as experience in this age is limited.
Adults
The usual starting dose is 500mg 2-3 times daily or 850mg 1-2 times daily. The maximum daily dose is 2- 3g taken in divided doses.
If you are taking insulin too, the doctor will advise you how to start Glucomet®.

CONTRA-INDICATIONS AND WARNINGS:
Glucomet® is contraindicated in:
- Patients with renal disease or renal dysfunction.
- Patients with known hypersensitivity to metformin.
- Acute or chronic metabolic acidosis with or without coma.
- Patients with kidney and liver problems
- If you are dehydrated.

Diabetic ketoacidosis should be treated with insulin.

Precautions:
Biguanides are inappropriate for patients with diabetic coma and ketoacidosis, or for those with severe infection, trauma, or other severe conditions where the biguanide is unlikely to control the hyperglycaemia; insulin should be administered in such situations. Glucomet® should also not be given to patients with heart failure, recent myocardial infarction, dehydration, alcoholism, or any other condition likely to predispose to lactic acidosis.

Adverse Effects:
Gastro-intestinal adverse effects include anorexia, nausea and diarrhoea. Patients may experience a metallic taste and there may be weight loss. Absorption of various substances including vitamin B_{12} may be impaired. Lactic acidosis, sometimes, fatal, has occurred.
Overdosage:
Acute poisoning may lead to the development of lactic acidosis and calls for intensive supportive therapy.
Interactions:
Use of Glucomet® with other drugs that lower blood glucose concentrations increases the risk of hypoglycaemia, while drugs that increase blood glucose may reduce the effect of Glucomet® therapy.
Taking other medicines
If you are taking any of the following medicines, your blood sugar level may need to be checked more often and your dose adjusted:
- Diuretics
- Beta-2- agonists such as salbutamol or terbutaline
- Corticosteroids

Alcohol may increase the risk of lactic acidosis as well as of hypoglycaemia. Care should be taken if Glucomet® is given with drugs that may impair renal function.
Pregnancy and breast-feeding:
Tell your doctor if you are, you think you might be or are planning to become pregnant, so that he or she may change your treatment.
This medicine is not recommended if you are breastfeeding or if you are planning to breast feed your baby.

PHARMACEUTICAL PRECAUTIONS:
Store in a dry place below 30ºC. Protect from light. Keep all medicines out of the reach of children.

LEGAL CATEGORY:
Prescription Only Medicine (POM)

®Regd. TM

COSMOS
Cosmos Limited,
Rangwe Rd; Off Lunga Lunga Rd,
Nairobi, Kenya

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