Glucomin XR
Metformin Hydrochloride

COMPOSITION
Glucomin XR 500 Tablet: Each extended release tablet contains Metformin Hydrochloride BP 500 mg.
Glucomin XR 1000 Tablet: Each extended release tablet contains Metformin Hydrochloride BP 1000 mg.

PHARMACOLOGY
Metformin is a biguanide type oral antihyperglycemic drug used in the management of type 2 diabetes. It lowers both basal and postprandial plasma glucose. Its mechanism of action is different from those of sulfonylureas and it does not produce hypoglycemia. Metformin decreases hepatic glucose production, decreases intestinal absorption of glucose and improves insulin sensitivity by an increase in peripheral glucose uptake and utilization.

INDICATION
Glucomin XR (Metformin Hydrochloride extended release tablet) is indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes. **Glucomin XR** is also indicated for use in combination therapy with an oral hypoglycemic agent or insulin when diet and exercise does not result in adequate glycemic control.

DOSAGE & ADMINISTRATION
Swallow **Glucomin XR** tablet whole and never crush, cut or chew.

Adult: The usual starting dose of **Glucomin XR** is 500 mg once daily with the evening meal. Dose should be increased in increments of 500 mg weekly, up to a maximum of 2000 mg once daily with the evening meal, alternatively increased to 1000 mg twice daily taken with meal. Patient receiving Metformin immediate release tablet may be switched to Metformin extended release tablet up to a maximum recommended daily dose.

Renal impaired patient: Do not use Metformin in patients with eGFR below 30 mL/min/1.73 m^2. Asses risk/benefit of counting if eGFR falls below 45 mL/min/1.73 m^2.

CONTRAINDICATION
Metformin Hydrochloride is contraindicated in patients with severe renal impairment, hypersensitivity to Metformin, acute or chronic metabolic acidosis and diabetic ketoacidosis, with or without coma.

WARNING & PRECAUTION
Metformin Hydrochloride is known to be substantially excreted by the kidney and the risk of Metformin accumulation and lactic acidosis increases with the degree of impairment of renal function. Metformin may lower vitamin B_{12} level. It also increases risk of hypoglycemia when use in combination with insulin or insulin secretagogue.

SIDE EFFECT
The most common side effects are diarrhea, nausea, vomiting, flatulence, asthenia, indigestion, abdominal discomfort and headache.

USE IN PREGNANCY & LACTATION
Pregnancy: Published studies have not reported a clear association with Metformin and major birth defects, miscarriage, or adverse maternal or fetal outcomes when Metformin was used during pregnancy.

Lactation: Metformin is excreted into human breast milk. No adverse effects were observed in breastfed newborns/infants. However, a decision on whether to discontinue breast-feeding should be made or taking into account the benefit of breast-feeding and the potential risk to adverse effect on the child.

USE IN CHILDREN & ADOLESCENT
Metformin extended release tablet has not been studied in children.

DRUG INTERACTION
Co-administration with Carbonic anhydrase (Topiramate, Zonisamide) may increase risk of lactic acidosis. Drugs (Ranolazine, Dolutegravir, Cimetidine) that reduce Metformin clearance may increase the accumulation of Metformin. Alcohol can potentiate the effect of Metformin on lactate metabolism.

OVERDOSE
Hypoglycemia has not been seen with Metformin doses up to 85 g, although lactic acidosis has occurred in such circumstances. Lactic acidosis is a medical emergency and must be treated in hospital. The most effective method to remove lactate and Metformin is hemodialysis.

STORAGE CONDITION
Keep below 30°C temperature, protected from light & moisture. Keep out of the reach of children.

HOW SUPPLIED
Glucomin XR 500 Tablet: Each box contains 40 tablets in Alu-Alu blister pack.
Glucomin XR 1000 Tablet: Each box contains 32 tablets in Alu-Alu blister pack.

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NIPRO JMI Pharma

Manufactured by:
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