

# Glucomin

Metformin Hydrochloride

## COMPOSITION

**Glucomin 500 Tablet:** Each film coated tablet contains Metformin Hydrochloride BP 500 mg.

**Glucomin 850 Tablet:** Each film coated tablet contains Metformin Hydrochloride BP 850 mg.

## PHARMACOLOGY

Glucomin (Metformin Hydrochloride) 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.

## INDICATIONS

Glucomin (Metformin Hydrochloride) as monotherapy, is indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes. Glucomin is also indicated for use in combination therapy with an oral hypoglycemic agent or insulin when diet and exercise plus the single agent do not result in adequate glycemic control.

## DOSAGE AND ADMINISTRATION

Dosage of Glucomin (Metformin Hydrochloride) must be individualized on the basis of both effectiveness and tolerance, while not exceeding the maximum recommended daily doses. The maximum recommended daily dose of Glucomin is 2550 mg in adults and 2000 mg in paediatric patients (10-16 years of age).

### Adults

The usual starting dose of Glucomin is 500 mg twice a day or 850 mg once a day, given with meals. Dosage increases should be made in increments of 500 mg weekly or 850 mg every 2 weeks, up to a total of 2000 mg per day, given in divided doses. For those patients requiring additional glycemic control, Glucomin may be given to a maximum daily dose of 2550 mg per day. Doses above 2000 mg may be better tolerated given three times a day with meals.

### Children

The usual starting dose of Glucomin is 500 mg twice a day, given with meals. Dosage increases should be made in increments of 500 mg weekly up to a maximum of 2000 mg per day, given in divided doses.

## CONTRAINDICATIONS

Metformin Hydrochloride is contraindicated in patients with renal dysfunction; cardiovascular collapse; acute myocardial infarction; diabetic ketoacidosis and known hypersensitivity to Metformin.

## WARNING AND 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. Thus, patients with serum creatinine levels above the upper limit of normal for their age should not receive Metformin.

## SIDE EFFECTS

Gastrointestinal symptoms (30% patients) such as diarrhea, nausea, vomiting, abdominal bloating, flatulence and anorexia are the most common reactions to Metformin. These symptoms are generally transient and resolve spontaneously during continued treatment. Because gastrointestinal symptoms during therapy initiation appear to be dose-related, they may be decreased by gradual dose escalation and by having patients taken Metformin with meals. Rarely lactic acidosis (approximately 0.03 cases/1000 patient-year) can occur due to Metformin accumulation during treatment with Metformin.

## USE IN PREGNANCY AND LACTATION

Pregnancy: Pregnancy category B. Safety in pregnant woman has not been established. Metformin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mother: It is not known whether Metformin is secreted in human milk. Because many drugs are excreted in human milk, it should not be administered to a breast feeding woman.

## USE IN CHILDREN AND ADOLESCENTS

Safety and effectiveness of it have not been established in (<10 years) paediatric patients.

## DRUG INTERACTIONS

Co-administration of Furosemide, Amiloride, Digoxin, Ranitidine, Triamterene and Trimethoprim with Metformin Hydrochloride increase the plasma metformin concentration. Thus, careful patient monitoring and dose adjustment of Metformin and/or the interfering drug is recommended in patients who are taking such drugs.

## OVERDOSAGE

Overdose of Metformin Hydrochloride has occurred, including ingestion of amounts greater than 50 grams. Metformin Hydrochloride may be removed by hemodialysis.

## STORAGE

Store below 30°C temperature in a cool and dry place. Keep out of the reach of children.

## HOW SUPPLIED

**Glucomin 500 Tablet:** Each box contains 50 tablets in Alu-PVC blister pack.

**Glucomin 850 Tablet:** Each box contains 50 tablets in Alu-PVC blister pack.