Glunor OD™

Metformin Hydrochloride BP Extended Release Tablet

DESCRIPTION

Glunor OD™ (Metformin Hydrochloride) Extended-Release Tablet is a biguanide type oral antihyperglycemic drug used in the management of type 2 diabetes. It lowers both basal and postprandial plasma glucose. Metformin decreases hepatic glucose production, decreases intestinal absorption of glucose and improves insulin sensitivity by increasing peripheral glucose uptake and utilization.

Metformin is developed as an extended-release formulation of Metformin Hydrochloride and designed for once-a-day oral administration using the Osmotic-controlled Release Oral delivery System (OROS).

INDICATIONS

Glunor OD™ Extended-Release Tablet is designed for once-a-day oral administration and deliver 500 mg or 1000 mg of Metformin Hydrochloride as monotherapy. It is indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes. **Glunor OD™** is also indicated for use in combination therapy with a sulfonylurea or insulin when diet and exercise plus the single agent do not result in adequate glycemic control.

DOSAGE AND ADMINISTRATION

Adults: Glunor OD™ should be taken with a full glass of water once daily with the evening meal. **Glunor OD™** should be started at a low dose, with gradual dose escalation, both to reduce gastrointestinal side effects and to permit identification of the minimum dose required for adequate glycemic control of the patient.

Dosage of **Glunor OD™** must be individualized on the basis of both effectiveness and tolerance, while not exceeding the maximum recommended daily dose. The maximum recommended daily dose of **Glunor OD™** Extended-Release Tablets in adults is 2500 mg.

The usual starting dose of **Glunor OD™** is 1000 mg, taken with a full glass of water once daily with the evening meal, although 500 mg may be utilized when clinically appropriate. Dosage increases should be made in increments of 500 mg weekly, up to a maximum of 2500 mg once daily with the evening meal.

Pediatrics – There is no pediatric information available for **Glunor OD™**.

CONTRAINDICATIONS

Metformin is contraindicated in patients with:

1. Severe renal impairment (eGFR below 30 mL/min/1.73 m^2)
2. Known hypersensitivity to Metformin.
3. Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma. Diabetic ketoacidosis should be treated with insulin.

PRECAUTIONS

Metformin 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 level above the upper limit of normal for their age should not receive Metformin.

USE IN PREGNANCY AND LACTATION

Pregnancy: 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.

To be dispensed only by the prescription of a registered physician.

DRUG INTERACTIONS

Co-administration of furosemide, nifedipine, amiloride, digoxin, ranitidine, triamterene, and trimethoprim with Metformin 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.

SIDE-EFFECTS

Gastrointestinal symptoms (30% patients) such as diarrhoea, 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. Becuase 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.

OVERDOSAGE

Hypoglycemia has not been seen even with ingestion of up to 85 grams of immediate-release Metformin, although lactic acidosis has occurred in such circumstances. Metformin is dialyzable with a clearance of up to 170 mL/min under good hemodynamic conditions. Therefore, hemodialysis may be useful for removal of accumulated drug from patients in whom Metformin over-dosage is suspected.

STORAGE CONDITION

Store at or below 30 °C temperature. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Glunor OD™ 500 Tablet: Box containing 5 strips of 6 tablets each. Each extended release tablet contains Metformin Hydrochloride BP 500 mg.
Glunor OD™ 1g Tablet: Box containing 5 strips of 6 tablets each. Each extended release tablet contains Metformin Hydrochloride BP 1000 mg.

SK+F
Manufactured by
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TM TRADEMARK
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