

Dialon[®]

Glimepiride USP Tablets

DESCRIPTION

Dialon[®] is the preparation of glimepiride. It is an oral blood-glucose lowering agent of sulfonylurea class. Glimepiride stimulates the secretion of insulin by the pancreas and may as well increase tissue sensitivity to insulin. The increased level of insulin metabolises blood sugar or glucose, thus reducing the hyperglycemia of diabetes. It is suitable for non insulin dependent diabetes mellitus (NIDDM).

INDICATIONS

- **Dialon[®]** is indicated as an adjunct to diet and exercise to lower the blood glucose in patients with non-insulin dependent (Type II) diabetes mellitus (NIDDM) whose hyperglycemia cannot be controlled by diet and exercise alone.
- **Dialon[®]** is also indicated for use in combination with insulin in patients whose hyperglycemia cannot be controlled by diet and exercise in conjunction with an oral hypoglycemic agent.

DOSAGE AND ADMINISTRATION

The usual starting dose as initial therapy is 1 to 2 mg once daily, administered with breakfast or the first main meal.

The usual maintenance dose is 1 to 4 mg once daily.

The maximum recommended dose is 8 mg once daily. After a dose of 2 mg is reached, increase the dose in increments of 2 mg or less at 1 to 2 week intervals based upon patient's blood glucose response.

For combination therapy with insulin: 8 mg once daily with the first main meal with low-dose insulin.

CONTRAINDICATIONS

- Known hypersensitivity to the drug
- Diabetic ketoacidosis, with or without coma
- Severe liver impairment, renal impairment
- During surgery
- Intercurrent illness (such as myocardial infarction, coma, infection, and trauma)
- Porphyria

USE IN PREGNANCY AND LACTATION

To avoid risk of harm to the child glimepiride must not be taken during pregnancy rather a changeover to insulin is necessary.

Patients planning a pregnancy must inform their physician, and should changeover to insulin for the entire course of pregnancy. As other sulfonylureas are excreted in human milk, glimepiride should be discontinued in nursing mothers.

PRECAUTIONS

The elderly are affected more by blood glucose lowering drugs, and lower dose of glimepiride may be needed. To avoid hypoglycemia, glimepiride should be taken once daily with breakfast or largest meal. Because glimepiride is excreted through the kidney and liver, people with renal or hepatic impairment may require dose adjustments.

SIDE-EFFECTS

Glimepiride is well tolerated. If side effects occur they include asthenia, dizziness, headache and nausea. Hypoglycemia can occur, but with less frequency than with glyburide. Hemolytic anaemia, urticaria & blurred vision may occur with the use of glimepiride.

DRUG INTERACTIONS

The hypoglycemic action of glimepiride may be potentiated by salicylates, sulfonamides, chloramphenicol, coumarins, probenecid, MAO inhibitors & β -adrenergic blocking agents. So caution should be taken during concomitant administration of such drugs with glimepiride.

PHARMACEUTICAL PRECAUTIONS

Keep away from light and moisture. Store not above 25°C temperature. Keep out of reach of children.

PACKAGING

Dialon® 1 Tablet : Box containing 5 strips of 10 tablets each. Each tablet contains Glimepiride USP 1 mg.

Dialon® 2 Tablet : Box containing 3 strips of 10 tablets each. Each tablet contains Glimepiride USP 2 mg.

Dialon® 3 Tablet : Box containing 2 strips of 10 tablets each. Each tablet contains Glimepiride USP 3 mg.

Dialon® 4 Tablet : Box containing 2 strips of 10 tablets each. Each tablet contains Glimepiride USP 4 mg.

SK+F

Manufactured by

ESKAYEF BANGLADESH LIMITED

DHAKA, BANGLADESH

® REGD. TRADEMARK

M/PM00097 V04