Glimitab® MP 1mg and 2mg

Glimepiride, Pioglitazone Hydrochloride & Metformin Hydrochloride Extended Release Tablets

COMPOSITION

Glimitab MP-1

Each tablet contains:	
Glimepiride	1 mg
Metformin Hydrochloride sustained-release	500 mg
Pioglitazone Hydrochloride	15 mg

Glimitab MP-2

Each tablet contains:	
Glimepiride	2 mg
Metformin Hydrochloride sustained-release	500 mg
Pioglitazone Hydrochloride	15 mg

THERAPEUTIC INDICATION: As third line treatment of Type II diabetes mellitus in adult patients when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control.

DOSAGE AND ADMINISTRATION: Usual starting dose for Glimepiride is 1-2mg od, usual maintenance dose is 1-4mg od, maximum dose is 8mg od. Pioglitazone may be initiated at 15mg or 30mg od, dose should not exceed 45mg od. Starting dose of Metformin Hydrochloride extended release tablets is 500mg od, maximum dose is 2000mg od. Well controlled patients on stable doses of the individual drugs can be switched to Glimitab MP 1/2 mg. To be given OD with the first meal of the day. Dosage must be individualized, not to exceed maximum recommended daily dose. Glimitab MP should not be crushed or chewed.

CONTRAINDICATIONS: In patients hypersensitive to Glimepiride, other sulfonylureas, other sulfonamides, metformin, pioglitazone or any of the excipients of Glimitab MP; pregnant women; breastfeeding women; diabetic ketoacidosis; diabetic pre-coma; renal failure or renal dysfunction; acute conditions with the potential to alter renal function (dehydration, severe infection, shock); acute or chronic disease which may cause tissue hypoxia (cardiac failure or respiratory failure, recent myocardial infarction, shock); hepatic insufficiency; acute alcohol intoxication; alcoholism; established New York Heart Association (NYHA) Class III or IV heart failure.

WARNINGS: In exceptional stress situations (e.g. trauma, surgery, febrile infections) blood glucose regulation may deteriorate, switch to insulin may be required; lactic acidosis, patient should be hospitalized immediately; fluid retention may occur that may lead to or exacerbate heart failure.

Advice for Health Care Professionals :

- Patients with active bladder cancer or with a history of bladder cancer and those with uninvestigated haematuria, should not receive Pioglitazone
- Prescribers should review the safety and efficacy of Pioglitazone in individuals after 3 – 6 months of treatment to ensure that only patients who are deriving benefit continue to be treated. Pioglitazone should be stopped in patients who do not respond adequately to treatment (eg reduction in HbA1C).
- Before starting Pioglitazone the following known risk factors for development of bladder cancer should be assessed in individuals : age, current or past history of smoking, exposure to some occupational or chemotherapeutic agents like cyclophosphamide, or previous irradiation of the pelvic region.
- Use in elderly patients should be considered carefully before and during treatment because the risk of bladder cancer increases with age. Elderly patients should start on lowest possible dose and be regularly monitored because of risk of bladder cancer and heart failure associated with Pioglitazone.

PRECAUTIONS: Risk of hypoglycaemia. Treatment of patients with G6PD can lead to hemolytic anaemia. Serum creatinine levels should be determined before initiating treatment and regularly thereafter. Intravascular administration of iodinated contrast materials in radiologic studies can lead to renal failure.

To be discontinued before elective surgery with general anaesthesia. Not to be used in patients with Type I DM and diabetic ketoacidosis. Not to be used in patients with NYHA Class III or IV cardiac status.

Caution in patients with oedema. Weight gain may be observed; may result in ovulation in pre-menopausal women, adequate contraception recommended. May cause decrease in heamoglobin and haematocrit. Should not be initiated if the patient exhibits clinical evidence of active liver disease. Macular edema has been reported and risk of fractures should be considered especially in female patients.

PREGNANCY & LACTATION: Not be taken during pregnancy / lactation. Must change over to insulin. Data insufficient to recommend use in paediatric patients.

ADVERSE REACTIONS: Glimepiride: Hypoglycaemia, eye disorders, gastrointestinal disorders, blood & lymphatic disorders, allergy. Metformin: Nausea, vomiting, diarrhoea, abdominal pain and loss of appetite (>10%) are very common. For Pioglitazone Hydrochloride: Can mainly cause upper respiratory infection, headache, sinusitis, myalgias, tooth disorder, pharyngitis, edema and weight gain.