# PREFORM
## Metformin Hydrochloride

**850 mg Tablet**
**500 mg SR Tablet**

**Description**
**PREFORM** (Metformin Hydrochloride) is an oral antihyperglycemic drug belongs to biguanide class used in the management of type -2 diabetes. It controls high blood sugar by decreasing hepatic glucose production, decreasing intestinal glucose absorption and improving insulin sensitivity through increasing peripheral glucose uptake and utilization. Unlike sulfonylureas, Metformin does not produce hypoglycemia. It is the drug of first choice in obese diabetic patients.

**Composition**
**PREFORM Tablet :** Each tablet contains Metformin Hydrochloride BP 850 mg.
**PREFORM -SR Tablet :** Each sustained release tablet contains Metformin Hydrochloride BP 500 mg

**Indication**
***As monotherapy :*** **PREFORM** (Metformin Hydrochloride) is indicated to lower blood glucose in patients with non-insulin-dependent diabetes mellitus (Type-2) whose hyperglycemia cannot be satisfactory managed on diet & exercise alone.
***In combination :*** **PREFORM** (Metformin Hydrochloride) may be used concomitantly with sulfonylurea, repaglinide, pioglitazone, acarbose or insulin when diet and monotherapy does not result in adequate gylcemic control.
***As an adjuvant :*** In insulin dependent diabetes mellitus (Type-1) **PREFORM** (Metformin Hydrochloride) may be given as an adjuvant to obese patients.

**Dosage and administration**
Dosage must be individualized on the basis of both effectiveness and tolerance. A lower recommended starting dose and gradually increased dose is advised to minimize GI symptoms.
**Dose of PREFORM tablet** two or three times daily or 850 mg once or twice daily with or after meals. Dosage can be increased gradually if necessary to 2000 to 3000 mg daily. Dosage increases should be made in increments of 500 mg weekly or 850 mg every 2 weeks given in divided doses. Doses above 2000 mg daily are associated with an increased incidence of GI adverse effects.
**Dose of PREFORM-SR tablet : PREFORM-SR tablet** is a sustained release formulation of Metformin, designed for once daily and better GI tolerance. The usual starting dose is once daily with the evening meal. Dosage increases should be made increments of 500 mg weekly, upto a maximum of 2000 mg once daily.

**Transfer from other antidiabetic therapy to PREFORM (Metformin) therapy :** When transferring patients from oral hypoglycemic agents other than chlorpropamide to **PREFORM** (Metformin Hydrochloride), no transition period generally is necessary. When transferring patients from chlorpropamide, care should be exercised during the first two weeks because of the prolonged retention of chlorpropamide in the body, leading to overlapping drug effects and possible hypoglycemia.
**Transfer from Metformin (PREFORM) to sustained release Metformin (PREFORM-SR) :** Patients currently treated with Metformin can be safely switched to sustained release Metformin (**PREFORM-SR**) once daily at the same total daily dose, up to 2000 mg once daily.

**Contraindication**
**PREFORM** (Metformin Hydrochloride) is contraindicated in patients with i) known hypersensitivity to Metformin Hydrochloride ii) Renal diseases or renal dysfunction iii) Congestive heart failure iv) Acute or chronic metabolic acidosis including diabetic ketoacidosis with or without coma v) Predisposition to lactic acidosis vi) Severe infection or trauma vii) Dehydration and alcohol dependence.

**Precaution**
Metformin should be used with caution in renal impairment, in hepatic impairment, in elderly people and in concomitant use with medications that may affect renal function, because there is a risk of Metformin accumulation and lactic acidosis. It should be used with caution in patients with congestive heart failure and MI who are at risk of hypoperfusion and hypoxemia, are at increased risk of lactic acidosis. Metformin should be promptly withheld in the presence of any condition associated with hypoxemia, dehydration, sepsis and in lactic acidosis. Metformin should be temporarily discontinued in patients undergoing radiologic studies involving the use of intravascular iodinated contrast materials, because use of such products can lead to acute alternation of renal function and lactic acidosis. There are reports of decrease of Vitamin $B_{12}$ level with continuous Metformin therapy in small percentage of patients; and advised to take Vitamin $B_{12}$ supplement. Alcohol intake is prohibited during Metformin treatment.

**Special population**
***Pregnant women :*** Pregnancy category B. Metformin should not be used during pregnancy unless clearly needed. ***Lactating mother :*** It is not known whether Metformin Hydrochloride is secreted in human milk. Because of the potential for serious adverse reactions in nursing infants from Metformin, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. ***Paediatric :*** The safety and effectiveness of Metformin for the treatment of type-2 diabetes have been established in paediatric patients age 10 years to 16 years. Below 10 years Metformin is not recommended. ***Geriatric :*** Because aging is associated with reduced renal function. Metformin should be used with caution as age increase and care should be taken in dose selection and monitoring renal function.

**Side effect**
Diarrhoea, nausea, vomiting, flatulence, asthenia, indigestion, abdominal discomfort, headache are the most common reaction to Metformin Hydrochloride. Lactic acidosis also rarely occurs.

**Drug interaction**
*Nifedipine :* Nifedipine appears to enhance the absorption of Metformin. *Thiazide and other diuretics, corticosteroids, pheniothiazines, thyroid products, estrogens, oral contraceptives, phenytoin, nicotinic acid, sympathomimetics, calcium channel blocking drugs and isoniazid :* tend to produce hyperglycemia and lead to loss of Metformin's glycemic control. *Cationic drugs that eliminated by renal tubular secretion (e.g., amiloride, digoxin, morphine, procainamide, quinidine, quinine, ranitidine, triamterene, trimethoprim or vancomycin) :* increase plasma concentration of Metformin.

**Overdose**
Overdose of Metformin Hydrochloride has occurred, when ingest greater than 50 gm. Hypoglycemia was reported in approximately 10% and lactic acidosis in 32% of Metformin overdose cases. Hemodialysis may be useful for removal of accumulated drug from patients in whom Metformin overdose is suspected.

**Storage**
Store in a cool dry place and away from light .keep out of the reach of children.

**How supplied**
**PREFORM Tablet :** Box contains 10 x 10 tablets in blister strips.
**PREFORM-SR Tablet :** Box contains 5 x 10 tablets in blister strips.

Apex pharma®

Manufactured by
**Apex Pharma Ltd.**
Shafipur, Gazipur