

Metformin Tablets BP

POM

COMPOSITION:

Each film coated tablet contains:

Metformin Hydrochloride BP 500 mg
Excipients Q.S.
Colour : Titanium Dioxide BP

Each film coated tablet contains:

Metformin Hydrochloride BP 850 mg
Excipients Q.S.
Colour : Titanium Dioxide BP

PHARMACOLOGICAL CLASSIFICATION:

Oral Anti-diabetic Agent (Biguanide)

PHARMACOLOGICAL ACTION:

Metformin hydrochloride decreases hepatic glucose production, decreasing intestinal absorption of glucose and improves insulin sensitivity (increases peripheral glucose uptake and utilization).

PHARMACOKINETIC:

- *Onset of action:* Within days; maximum effects up to 2 weeks
- *Distribution:* Vd: 654 ± 358 L; partitions into erythrocytes
- *Protein binding:* Negligible
- *Metabolism:* Not metabolized by the liver
- *Bioavailability:* Absolute: Fasting: 50% to 60%
- *Half-life elimination:* Plasma: 4-9 hours
- *Time to peak, serum:* Extended release: 7 hours (range: 4-8 hours)
- *Excretion:* Urine (90% as unchanged drug; active secretion)

INDICATIONS:

Metformin hydrochloride tablets are indicated for the management of type 2 diabetes mellitus (noninsulin dependent, NIDDM) as monotherapy when hyperglycemia cannot be managed with diet and exercise alone. In adults, may be used concomitantly with a sulfonyleurea or insulin to improve glycaemic control.

CONTRAINDICATIONS:

Metformin hydrochloride tablets are contraindicated for patient with

- Renal disease or renal dysfunction (e.g., as suggested by serum creatinine levels 1.5 mg/dL [males], 1.4 mg/dL [females] or abnormal creatinine clearance), which may also result from conditions such as cardiovascular collapse (shock), acute myocardial infarction, and septicemia.
- Known hypersensitivity to Metformin, or any of the ingredients of the Metformin Hydrochloride tablets.
- Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma. Diabetic ketoacidosis should be treated with insulin.
- Temporarily discontinue in patients undergoing radiologic studies in which intravascular iodinated contrast media are utilized, because use of such products may result in acute alteration of renal function.

SPECIAL PRECAUTIONS AND WARNING:

Use Metformin hydrochloride with caution in patients with

- Cardiovascular mortality as oral hypoglycemic drugs may be associated with an increased cardiovascular mortality as compared to treatment with diet alone or diet plus insulin.
- Lactic acidosis is a rare, but potentially severe consequence of therapy with Metformin.
- *Hepatic impairment:* Avoid use in patients with impaired liver function due to potential for lactic acidosis.
- *Renal impairment:* Metformin is substantially excreted by the kidney; patients with renal function below the limit of normal for their age should not receive therapy.
- *Elderly:* Metformin should not be initiated in patient ≥ 80 years of age unless normal renal function is confirmed.
- *Stress-related states:* It may be necessary to discontinue Metformin and administer insulin if the patient is exposed to stress (fever, trauma, infection, surgery).
- *Pregnancy:* Available information suggests that Metformin use during pregnancy may be safe as long as good glycaemic control is maintained. Metformin Hydrochloride is prescribed unlabeled for the treatment of Gestational Diabetes Mellitus (GDM); Polycystic Ovary Syndrome (PCOS). However the use of oral agents is generally not recommended as routine management of GDM or type 2 diabetes mellitus during pregnancy. Metformin hydrochloride tablets should not be used unless the potential benefit outweighs the potential risk to fetus.
- *Lactation:* Metformin Hydrochloride tablets are not recommended for use in lactating mothers as it excretes into breast milk.

DOSAGE AND DIRECTIONS FOR USE:

There is no fixed dosage regimen for the management of hyperglycemia in patient with type 2 diabetes with Metformin hydrochloride tablets. Dosage of Metformin hydrochloride tablets should be individualized on the basis of both effectiveness and tolerance, while not exceeding the maximum recommended daily doses. The maximum recommended daily dose for Metformin hydrochloride tablet is 2550 mg for adult and 2000mg for children (10-16 years of age).

Adult: Initial 500 mg twice daily or 850 mg once daily; titrate in increments of 500 mg weekly or 850 mg every other week; may also

titrate from 500 mg twice a day to 850 mg twice a day after 2 weeks with breakfast or first main meal of the day and gradual increased dosage as directed by physician.

Children 10-16 years: Initial: 500 mg twice daily; increases in daily dosage should be made in increments of 500 mg at weekly intervals, given in divided doses, up to a maximum of 2000 mg/day.

ADVERSE EFFECTS:

- Gastrointestinal: Diarrhea, nausea, vomiting, flatulence Indigestion, abdominal discomfort, abdominal distention, abnormal stools, constipation, dyspepsia/ heartburn, taste disorder
- Neuromuscular & skeletal: Weakness, Myalgia
- Cardiovascular: Chest discomfort, flushing, palpitation
- Central nervous system: Headache, chills, dizziness, lightheadedness
- Dermatologic: Rash
- Endocrine & metabolic: Hypoglycemia
- Respiratory: Dyspnea, upper respiratory tract infection
- Miscellaneous: Diaphoresis increased, vitamin B12 levels decreased, flu-like syndrome, nail disorder

DRUG INTERACTIONS:

Drug	Interaction
Amiloride, Digoxin, Morphine, Procainamide, Quinidine, Quinine, Ranitidine, Triamterene, Vancomycin ACE inhibitors	Compete with Metformin hydrochloride for substantial tubular secretion Potential risk of hypoglycemia/hyperglycemia when ACE inhibitor therapy is initiated/withdrawn Antagonize Hypoglycemic Effects of Metformin hydrochloride
Calcium-channel blocking agents, corticosteroids, thiazide diuretics, estrogens and progestins (e.g., oral contraceptives), isoniazid, niacin, phenothiazines, sympathomimetic agents (e.g., albuterol, epinephrine, terbutaline)	
Alcohol	Increased risk of hypoglycemia and lactic acidosis
Cimetidine	Possible decreased excretion of Metformin hydrochloride
Clomiphene	Possible resumption of ovulation in premenopausal patients with polycystic ovary syndrome
Furosemide	Increased plasma concentrations of Metformin hydrochloride and furosemide
Glyburide	Variable decreases in AUC and peak blood concentration of Glyburide
Nifedipine	Enhanced absorption and increased urinary excretion of Metformin
Thiazide diuretics	May exacerbate diabetes mellitus

OVERDOSAGE:

Mild hypoglycemic symptoms without loss of consciousness or neurologic findings should be treated aggressively with oral glucose and adjustments in drug dosage and/or meal patterns. Close monitoring should continue until the physician is assured that the patient is out of danger.

Severe hypoglycemic reactions with coma, seizure, or other neurological impairment occur infrequently, but constitute medical emergencies requiring immediate hospitalization. If hypoglycemic coma is diagnosed or suspected, the patient should be given a rapid IV injection of concentrated (50%) glucose solution. This should be followed by a continuous infusion of a more dilute (10%) glucose solution at a rate that will maintain the blood glucose level above 100 mg/dL. Patients should be closely monitored for a minimum of 24 to 48 hours, because hypoglycemia may recur after apparent clinical recovery.

Lactic acidosis is a rare, but serious, metabolic complication that can occur if Metformin accumulates during treatment due to overdosing. Strict monitoring should be continued until the doctor is sure that the patient is out of danger.

PRESENTATION:

Blister pack / Jar Pack

STORAGE CONDITION:

Store below 30 °C. Protect from light.

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Manufactured by :



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