

Goodmet

Metformin Hydrochloride BP

Composition

Goodmet 500 tablet: Each film coated tablet contains Metformin Hydrochloride BP 500 mg.

Goodmet 850 tablet: Each film coated tablet contains Metformin Hydrochloride BP 850 mg.

Pharmacology

Goodmet (Metformin Hydrochloride), a dimethylbiguanide, is an orally active antidiabetic drug. Biguanides such as Goodmet (Metformin Hydrochloride) lower blood glucose level in patients with diabetes mellitus without increasing insulin secretion from pancreatic beta cells. Goodmet (Metformin Hydrochloride) decreases hepatic glucose production, decreases intestinal absorption of glucose and improves insulin sensitivity (increases peripheral glucose uptake and utilization). Goodmet (Metformin Hydrochloride) does not produce hypoglycemia in diabetic and nondiabetic subjects (except in special circumstances).

Indications

In NIDDM (Non-insulin dependent diabetes mellitus or type-2 diabetes): As monotherapy, as an adjunct to diet to lower blood glucose in patients with NIDDM whose hyperglycemia can not be satisfactorily managed on diet alone. Goodmet (Metformin Hydrochloride) may be used concomitantly with a sulphonylurea when diet and metformin or sulphonylurea alone do not result in adequate glycemic control.

In IDDM (Insulin dependent diabetes mellitus or type-1 diabetes): As an adjunct therapy in combination with insulin.

Dose and Administration

There is no fixed dose regimen for the management of hyperglycemia in diabetes mellitus with Goodmet (Metformin Hydrochloride). Dose must be individualized on the basis of both effectiveness and tolerance while not exceeding the maximum recommended daily dose of 2550 mg.

Goodmet (Metformin Hydrochloride) 500 mg: The usual starting dose is one 500 mg tablet twice daily, given with the morning or evening meals. Dose increase should be made in increments of 500 mg every week, given in divided doses, up to a maximum of 2550 mg/day. Metformin can be administered twice a day up to 2000 mg/day (e.g. 1000 mg twice daily with morning & evening meals). If a 2500 mg daily dose is required, it may be better tolerated given three times daily with meals.

Goodmet (Metformin Hydrochloride) 850 mg: The usual starting dose is one 850 mg tablet daily given with the morning meals. Dose increase should be made in increments of 850 mg every other week, given in divided doses, up to a maximum of 2550 mg/day. The usual maintenance dose is 850 mg twice daily with the morning and evening meals. When necessary, patients may be given 850 mg 3 times daily with meals, or as directed by the physicians.

Contraindication

Goodmet (Metformin Hydrochloride) is contraindicated in

- Renal disease or dysfunction which may also result from conditions such as cardiovascular collapse (shock), acute MI & septicemia.
- Patients undergoing radiologic studies involving parenteral administration of iodinated contrast meals.
- Hypersensitivity to Metformin Hydrochloride.
- Acute or chronic metabolic acidosis including diabetic ketoacidosis with or without coma.

Warning and precautions

- Monitoring: Before initiation of therapy and at least annually thereafter, renal function must be assessed and verified. Patients previously well controlled by Goodmet (Metformin Hydrochloride) but develop abnormalities in medical tests should be further evaluated

for evidence of ketoacidosis or lactic acidosis. Response to all diabetic therapies by periodic measurement of blood glucose and glycosylated hemoglobin should be monitored. Initial and periodic monitoring of haematologic parameters and renal function should be performed at least on annual basis.

- Hypoxic states: Cardiovascular collapse (shock), acute CHF, acute MI and other conditions characterized by hypoxemia have been associated with lactic acidosis and may also cause prerenal azotemia. If such events occur, Goodmet (Metformin Hydrochloride) must be discontinued.

- Surgical procedure: Temporarily Goodmet (Metformin Hydrochloride) has to be suspended for surgical procedures.

- Vitamin B₁₂ levels: Certain individuals with inadequate Vitamin B₁₂ or calcium intake or absorption may be predisposed to developing subnormal Vitamin B₁₂ levels. In these patients, routine serum Vitamin B₁₂ measurements as 2 or 3-year intervals may be useful.

Side Effects

Metformin Hydrochloride, the active ingredient in Goodmet (Metformin Hydrochloride) can cause a rare but serious condition called lactic acidosis that can cause death. Common side effects include diarrhea, nausea and upset stomach. Goodmet (Metformin Hydrochloride) rarely causes hypoglycemia.

Use in pregnancy and lactation

Pregnancy Category B. The drug has been used in pregnant women without any particular problem. Nevertheless, it is generally regarded as a contraindication in pregnancy and insulin should be used in all pregnant diabetic women.

Goodmet (Metformin Hydrochloride) enters breast milk in small amounts and is best avoided in lactating mothers.

Use in children and adolescents

Safety & efficacy of Goodmet (Metformin Hydrochloride) in children have not been established. Use of Goodmet (Metformin Hydrochloride) in adolescents is supported by evidences from clinical studies, demonstrating a similar response in glycemic control to that seen in adults.

Drug Interaction

Drugs that may affect Goodmet (Metformin Hydrochloride) include Alcohol, Cationic drugs, Cimetidine, Furosemide, Iodinated contrast material and Nifedipine. Drugs that may be affected by Goodmet (Metformin Hydrochloride) include Glyburide and Furosemide. Certain drugs tend to produce hyperglycemia and may lead to loss of glycemic control such as Thiazide and other diuretics, Corticosteroids, Phenothiazines, Thyroid products, Estrogens, Oral contraceptives, Phenytoin, Nicotinic acid, Sympathomimetics, Calcium channel blockers, Isoniazide and Beta-adrenergic blockers.

Overdose

Hypoglycemia has not been seen even with ingestion of amounts greater than 50 grams of Metformin Hydrochloride, although lactic acidosis has occurred in such circumstances. Hemodialysis may be useful for removal of accumulated drug from patients to whom Metformin Hydrochloride overdose is suspected.

Storage

Store below 30 °C, protected from light and moisture. Keep all medicines out of the reach of children.

Packing

Goodmet 500 tablet: Each box contains 6x10's tablets in Alu-PVC blister packs.

Goodmet 850 tablet: Each box contains 5x10's tablets in Alu-PVC blister packs.



Manufactured by:

Goodman Pharmaceuticals Ltd.

Better Health For All
Bhangnathi, Sreepur, Gazipur, Bangladesh