

Sugamet™

Metformin Hydrochloride Tablet

Presentation

Sugamet™ 500 Tablet: Each film coated tablet contains Metformin Hydrochloride EP 500 mg.

Sugamet™ 850 Tablet: Each film coated tablet contains Metformin Hydrochloride EP 850 mg.

Sugamet™ XR 500 Tablet: Each extended release tablet contains Metformin Hydrochloride BP 500 mg.

Indications

Sugamet™ (Metformin Hydrochloride tablet) is indicated as an adjunct to diet and exercise to improve glycaemic control in children and adults with type 2 diabetes mellitus.

Sugamet™ XR 500 (Metformin Hydrochloride extended release tablet) is indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus.

Dosage & Administration

Adults: Starting dose of Sugamet™ (Metformin Hydrochloride Tablet) is 500 mg twice a day or 850 mg once a day, given with meals. Dosage increases should be made in increments of 500 mg weekly or 850 mg every 2 weeks, up to a total of 2,000 mg per day, given in divided doses. Starting dose of Sugamet™ XR (Metformin Hydrochloride Extended Release Tablet) is 500 mg once daily with the evening meal. Dosage increases should be made in increments of 500 mg weekly, up to a maximum of 2,000 mg once daily with the evening meal. If glycaemic control is not achieved on Sugamet™ XR 2,000 mg once daily, a trial of Sugamet™ XR 1,000 mg twice daily should be considered.

Pediatrics: Starting dose of Sugamet™ is 500 mg twice a day, given with meals. Dosage increases should be made in increments of 500 mg weekly up to a maximum of 2,000 mg per day, given in divided doses.

Side effects

Diarrhea, nausea, vomiting, flatulence, asthenia, indigestion, abdominal discomfort, headache etc.

Caution

Metformin is known to be substantially excreted by the kidney and the risk of Metformin accumulation and lactic acidosis increase with the degree of impairment of renal function. Thus, patients with serum creatinine levels above the upper limit of normal for their age should not receive Metformin. In patients with advanced age, Metformin should be carefully titrated to establish the minimum dose for adequate glycaemic effect, because aging is associated with reduced renal function.

Contraindication

Metformin is contraindicated in patients with-

1. Renal disease or renal dysfunction (e.g., as suggested by serum creatinine levels >1.5 mg/dL [male], >1.4 mg/dL [female] or abnormal creatinine clearance).
2. Known hypersensitivity to Metformin Hydrochloride or to any excipient of this product.
3. Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma.

Drug Interaction

No information is available about the interaction of Metformin and furosemide when co-administered chronically. Nifedipine appears to enhance the absorption of Metformin. Metformin had minimal effects on Nifedipine. Cationic drugs (e.g., Amiloride, Digoxin, Morphine, Procainamide, Quinidine, Quinine, Ranitidine, Triamterene, Trimethoprim, or Vancomycin) that are eliminated by renal tubular secretion theoretically have the potential for interaction with Metformin by competing for common renal tubular transport systems. Metformin had no effect on Cimetidine pharmacokinetics. Certain drugs such as thiazides and other Diuretics, Corticosteroids, Phenothiazines, Thyroid products, Estrogens, Oral contraceptives, Phenytoin, Nicotinic acid, Sympathomimetics, Calcium Channel Blocking drugs, and Isoniazid tend to produce hyperglycaemia and may lead to loss of glycaemic control.

Use in Pregnancy and Lactation

Pregnancy Category B. Most experts recommend that insulin should be used during pregnancy to maintain blood glucose levels as close to normal as possible. Both Metformin immediate and extended release tablets should not be used during pregnancy unless clearly needed. Because the potential for hypoglycaemia in nursing infants may exist, 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.

Storage

Store in a cool (below 30°C) and dry place, away from light. Keep out of the reach of children.

Packaging

Sugamet™ 500 Tablet: Each box contains 10 blister packs with 10 tablets in each strip.

Sugamet™ 850 Tablet: Each box contains 5 blister packs with 10 tablets in each strip.

Sugamet™ XR 500 Tablet: Each box contains 5 blister packs with 10 tablets in each strip.

Manufactured by:

 **GENERAL**
Pharmaceuticals Ltd.
Mouchak, Kalliakair, Gazipur, Bangladesh