

Sugamet™ XR

Metformin Hydrochloride Extended Release Tablet

Presentation

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

Sugamet™ XR 1000 Tablet: Each extended release tablet contains Metformin Hydrochloride BP 1000 mg

Pharmacodynamic properties

Sugamet™ XR is a biguanide with anti-hyperglycemic effects, lowering both basal and postprandial plasma glucose. It does not stimulate insulin secretion and therefore does not produce hypoglycemia.

Pharmacokinetic properties

Absorption: After an oral dose, Metformin Hydrochloride Extended Release Tablet absorption is significantly delayed compared to the immediate release tablet with a T_{max} at 7 hours.

Distribution: Plasma protein binding is negligible. Metformin Hydrochloride Extended Release Tablet partitions into erythrocytes. The blood peak is lower than the plasma peak and appears at approximately the same time.

Metabolism: It is excreted unchanged in the urine and does not undergo hepatic metabolism (no metabolites have been identified in humans) nor biliary excretion.

Elimination: Renal clearance is approximately 3.5 times greater than creatinine clearance, which indicates that tubular secretion is the major route of Metformin Hydrochloride Extended Release Tablet. Following oral administration, approximately 90% of the absorbed drug is eliminated via the renal route within the first 24 hours.

Indications

Sugamet™ XR (Metformin Hydrochloride Extended Release 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 (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.

Special Instructions

- Swallow this medicine whole, without splitting, chewing or crushing them. This medicine is usually taken once daily with the evening food.
- A missed dose should be taken with food as soon as you remember it. Avoid taking a double dose to make up for a missed dose.

Dosage & Administration

Adults: 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™ XR 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. Sugamet™ XR tablet has not been studied in children. Metformin Hydrochloride Extended Release should not be used for patients with renal impairment (eGFR < 30 mL/minute/ 1.73 m²).

Contraindications

Metformin Hydrochloride Extended Release Tablet is contraindicated in patients with-

- 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).
- Known hypersensitivity to Metformin Hydrochloride Extended Release Tablet or to any excipient of this product.
- Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma.

Side Effects

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

Precautions

Metformin Hydrochloride Extended Release Tablet is known to be substantially excreted by the kidney and the risk of Metformin Hydrochloride Extended Release Tablet 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 Hydrochloride Extended Release Tablet. In patients with advanced age, Metformin Hydrochloride Extended Release Tablet should be carefully titrated to establish the minimum dose for adequate glycaemic effect, because aging is associated with reduced renal function.

Drug Interactions

No information is available about the interaction of Metformin Hydrochloride Extended Release Tablet and furosemide when co-administered chronically. Nifedipine appears to enhance the absorption of Metformin Hydrochloride Extended Release Tablet. Metformin Hydrochloride Extended Release Tablet 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 Hydrochloride Extended Release Tablet by competing for common renal tubular transport systems. Metformin Hydrochloride Extended Release Tablet 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 Hydrochloride 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.

Overdose

Overdose can cause lactic acidosis. Symptoms of overdose may include: severe drowsiness, severe nausea/vomiting/diarrhea, rapid breathing, slow/irregular heartbeat. If you think there has been an overdose, contact with your nearby healthcare center.

Storage

Store below 30°C and dry place, away from light. Keep out of the reach of children.

Packing

Sugamet™ XR 500 Tablet: Each box contains 6 blister packs with each blister of 10 tablets.

Sugamet™ XR 1000 Tablet: Each box contains 3 blister packs with each blister of 10 tablets.

Manufactured by:

 **GENERAL**
Pharmaceuticals Ltd.
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