

Xelmet

Metformin Hydrochloride BP

Composition

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

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

Xelmet XR 500 tablet: Each extended release tablet contains Metformin Hydrochloride BP 500 mg.

Xelmet XR 1 gm tablet: Each extended release tablet contains Metformin Hydrochloride BP 1gm.

Description

Xelmet is a biguanide type oral antihyperglycemic drug used in the management of type 2 diabetes. It lowers both basal and postprandial plasma glucose. Its mechanism of action is different from those of sulfonylureas and it does not produce hypoglycemia. **Xelmet** decreases hepatic glucose production, decreases intestinal absorption of glucose and improves insulin sensitivity by an increase in peripheral glucose uptake and utilization.

Indication

Xelmet, as monotherapy, is indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes. **Xelmet** is also indicated for use in combination therapy with an oral hypoglycemic agent or insulin when diet and exercise plus the single agent do not result in adequate glycemic control.

Dosage and Administration

Dosage of **Xelmet** or **Xelmet XR** must be individualized on the basis of both effectiveness and tolerance, while not exceeding the maximum recommended daily doses. The maximum recommended daily dose of **Xelmet** is 2550 mg in adults and 2000 mg in pediatric patients (10-16 years of age). The maximum recommended daily dose of **Xelmet XR** in adults is 2000 mg. **Xelmet** should be given in divided doses with meals while **Xelmet XR** should generally be given once daily with the evening meal. **Xelmet XR** tablet must be swallowed whole and never be crushed or chewed. **Xelmet** or **Xelmet XR** should be started at a low dose, with gradual dose escalation, both to reduce gastrointestinal side effects and to permit identification of the minimum dose required for adequate glycemic control of the patient.

Recommended Dosing Schedule

Adults

The usual starting dose of **Xelmet** is 500 mg two or three times a day, or 850 mg once or two times 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 2000 mg per day, given in divided doses. For those patients requiring additional glycemic control, **Xelmet** may be given to a maximum daily dose of 2550 mg per day. Doses above 2000 mg may be better tolerated given three times a day with meals. The usual starting dose of **Xelmet XR** 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 2000 mg daily. Patients receiving **Xelmet** treatment may be safely switched to **Xelmet XR** once daily at the same total daily dose, up to 2000 mg daily.

Pediatrics

The usual starting dose of **Xelmet** 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 2000 mg per day, given in divided doses. Safety and effectiveness of **Xelmet** in pediatric patients below 10 years have not been established.

Side effects

Gastrointestinal symptoms (30% patients) such as diarrhea, nausea, vomiting, abdominal bloating, flatulence and anorexia are the most common reactions to Metformin. These symptoms are generally transient and resolve spontaneously during continued treatment. Because gastrointestinal symptoms during therapy initiation appear to be dose-related, they may be decreased by gradual dose escalation and by having patients taken Metformin with meals. Rarely lactic acidosis (approximately 0.03 cases/1000 patient-year) can occur due to Metformin accumulation during treatment with Metformin.

Contraindication

Metformin is contraindicated in patients with renal dysfunction; cardiovascular collapse; acute myocardial infarction; diabetic ketoacidosis and known hypersensitivity to Metformin.

Precautions

Metformin is known to be substantially excreted by the kidney and the risk of Metformin accumulation and lactic acidosis increases 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.

Use in Pregnancy and Lactation

Pregnancy: Safety in pregnant woman has not been established. Metformin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mother: It is not known whether Metformin is secreted in human milk. Because many drugs are excreted in human milk, it should not be administered to a breast feeding woman.

Drug Interactions

Co-administration of Frusemide, Nifedipine, Amiloride, Digoxin, Ranitidine, Triamterene, and Trimethoprim with Metformin increase the plasma Metformin concentration. Thus, careful patient monitoring and dose adjustment of Metformin and/or the interfering drug is recommended in patients who are taking such drugs.

Overdosage

Hypoglycemia has not been seen even with ingestion of up to 85 grams of Metformin, although lactic acidosis has occurred in such circumstances. Hemodialysis may be useful for removal of accumulated drug from patients in whom Metformin overdose is suspected.

Storage

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

Commercial pack

Xelmet 500 tablet: Each commercial box contains 60 tablets in Alu-PVC blister pack.

Xelmet 850 tablet: Each commercial box contains 60 tablets in Alu-PVC blister pack.

Xelmet XR 500 tablet: Each commercial box contains 28 tablets in Alu-Alu blister pack.

Xelmet XR 1 gm tablet: Each commercial box contains 28 tablets in Alu-Alu blister pack.

Manufactured By

BEACON®
Pharmaceuticals PLC

Bhaluka, Mymensingh, Bangladesh