

Composition

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

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

Pharmacology

Wellmet 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. Wellmet decreases hepatic glucose production, decreases intestinal absorption of glucose and improves insulin sensitivity by an increase in peripheral glucose uptake and utilization.

Indication

Wellmet, as monotherapy, is indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes. Wellmet 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.

Dose & Administration

a) Route of administration: Oral

Dosage of Wellmet 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 Wellmet is 2550 mg in adults and 2000 mg in pediatric patients (10-16 years of age).

Adults: The usual starting dose of Wellmet 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 2000 mg per day, given in divided doses. For those patients requiring additional glycemic control, Wellmet 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.

Pediatrics: The usual starting dose of Wellmet 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.

Contraindication

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

Warning & Precaution

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.

Side effects

a) Common: 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.

b) Rare: lactic acidosis (approximately 0.03 cases/1000 patient-year) can occur due to Metformin accumulation during treatment with 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.

Use in Children & Adolescents:

The diagnosis of type 2 diabetes mellitus should be confirmed before treatment with metformin is initiated. Careful follow-up, especially in prepubescent children, is recommended. Particular caution is recommended when prescribing to children aged between 10 and 12 years.

Drug Interactions

a) With medicine: 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.

b) With food and others: Food decreases the extent and delays the time to achieve maximum absorption. The plasma peak concentration may be 40% lower with food administration.

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. Protect from light and moisture. Keep all medicines out of reach of children.

Packing

Wellmet 500 Tablet: Each box contains 30 (3 X 10's) tablets in blister pack.

Wellmet 850 Tablet: Each box contains 30 (3 X 10's) tablets in blister pack.