Metform®

Metformin

Description

Metform® is a preparation of Metformin Hydrochloride. It is a biguanide type oral antihyperglycemic agent used in the management of type 2 diabetes mellitus. It lowers both basal and postprandial plasma glucose. Its mechanism of action is different from those of sulfonylureas and it does not produce hypoglycemia. Metformin acts by decreasing intestinal absorption of glucose, reducing hepatic glucose production, and improves insulin sensitivity thus enhancing peripheral glucose uptake and utilization of glucose.

Indications

Metform® as monotherapy is indicated as an adjunct to diet to lower blood glucose in patients with non-insulin-dependent diabetes mellitus (NIDDM) whose hyperglycemia cannot be satisfactorily managed on diet alone. Metform® is also indicated for use concomitantly with a sulfonylurea when diet and Metformin Hydrochloride or sulfonylureas alone do not result in adequate glycemic control.

Dosage and administration:

Adults:

Metform® 500 mg & 850mg*:* The usual starting dose of Metformin 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. Patients can also be titrated from 500 mg twice a day to 850 mg twice a day after 2 weeks. For those patients requiring additional glycemic control, Metform® 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.

Metform® ER : The usual starting dose of Metform® ER (Metformin Hydrochloride extended-release tablets) 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 once daily with the evening meal. If glycemic control is not achieved on Metform® ER 2000 mg once daily, a trial of Metform® ER 1000 mg twice daily should be considered. If higher doses of Metformin are required, Metform® should be used at total daily doses up to 2550 mg administered in divided daily doses, as described above.

Concomitant Metform® or Metform® ER and oral sulfonylurea therapy in adult patients:

If patients have not responded to four weeks of the maximum dose of Metform® & Metform® ER monotherapy, consideration should be given to gradual addition of an oral sulfonylurea.

Concomitant Metform® or Metform® ER and Insulin Therapy in Adult Patients:

The current insulin dose should be continued upon initiation of Metform® or Metform® ER therapy. Metform® or Metform® ER therapy should be initiated at 500 mg once daily in patients on insulin therapy. For patients not responding adequately, the dose of Metform® or Metform® ER should be increased by 500 mg after approximately 1 week and by 500 mg every week thereafter until adequate glycemic control is achieved. The maximum recommended daily dose is 2500 mg for Metform® and 2000 mg for Metform® ER.

Children

The usual starting dose of Metform® 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 Metform® ER in pediatric patients below 10 years has not been established.

Geriatric Use:

Metform® should only be used in patients with normal renal function. Care should be taken in dose selection and should be based on careful and regular monitoring of renal function.

Use in pregnancy & lactation

Safety of Metform® in pregnant woman has not been established. Metform® should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known whether Metform® is secreted in human milk. Because many drugs are excreted in human milk, it should not be administered to a breast-feeding woman.

Side-effects

The most common side effect of Metformin is diarrhoea, nausea, vomiting, abdominal bloating, flatulence, and anorexia. Lactic acidosis also rarely occurs. Long- term use of Metformin has been associated with malabsorption of vitamin B_{12}

Contraindications

Metformin is contraindicated in patients with hypersensitivity to Metformin or to any of its ingredients. It is also contraindicated in renal disease or dysfunction, congestive heart failure, acute myocardial infarction and diabetic ketoacidosis.

Precautions

Metformin Hydrochloride therapy should be temporarily suspended for any surgical procedure (except minor procedures not associated with restricted intake of food and fluids) and should not be restarted until the patient's oral intake has resumed and renal function has been evaluated as normal. It should be used with caution in case of excessive alcohol intake and hepatic insufficiency. 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. It should be temporarily discontinued in patients undergoing radiologic studies involving intravascular administration of iodinated contrast materials, because use of such products may result in acute alteration of renal function.

Drug Interactions

Plasma concentration of Metformin is increased if Metformin co-administrates with furosemide, nifedipine, amiloride, digoxin, ranitidine, triamterene, and trimethoprim. Thus, careful patient monitoring and dose adjustment of Metformin and/or the interfering drug is recommended in patients who are taking such drugs. When such drugs are administered to a patient receiving Metformin, the patient should be closely observed to maintain adequate glycemic control.

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 over dosage is suspected.

Pharmaceutical precautions

Store in a cool and dry place. Protect from light. Keep out of reach of children.

Presentation :

Metform® 500: A white colored, round shaped film coated tablet. Each coated tablet contains Metformin Hydrochloride BP 500mg
Metform® 850: A white colored, oblong shaped film coated tablet. Each coated tablet contains Metformin Hydrochloride BP 850mg
Metform® ER tablet: A white colored, caplet shaped film coated tablet. Each extended release tablet contains Metformin Hydrochloride BP 1000mg

Package quantities

Metform® 500:Carton of 100 tablets in Alu-PVC blister.
Metform® 850: Carton of 50 tablets in Alu-PVC blister.
Metform® ER :Carton of 32 tablets in Alu-PVC blister.

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