BIGMET®

Metformin Hydrochloride
Film Coated Tablet

Composition

Each Film coated tablet contains Metformin hydrochloride BP 500 mg & 850 mg

Indications

It is used in the management of non-insulin dependent diabetes mellitus (NIDDM), Metformin is the drug of first choice in obese (over weight) patients in whom strict dieting has failed to control diabetes. It is also used when diabetes is inadequately controlled with sulphonylurea treatment.
In insulin-dependent diabetes, Bigment may be given as an adjuvant to patients whose symptoms are poorly controlled.

Properties

Metformin the only available biguanide, has a different mode of action from the sulphonylureas and is not interchangeable with them. It exerts its effect mainly by decreasing gluconeogenesis and by increasing peripheral utilization of glucose. Metformin has a modest favourable effect on serum lipids, which are often abnormal in NIDDM patients. In clinical studies particularly when baseline levels were abnormally elevated, Bigmet alone or in combination with a sulfonylurea, lowered mean fasting serum triglycerides, total cholesterol & LDL cholesterol levels & had no adverse effect on other lipid levels.

Pharmacokinetics

Metformin hydrochloride is slowly and incompletely absorbed from the gastrointestinal tract; the absolute bioavailability of a single 500 mg dose is reported to be about 50 to 60%, although this is reduced somewhat if taken with food. Following absorption plasma protein binding is negligible and it is excreted unchanged in the urine. The plasma elimination half life is reported to range from about 2 to 6 hours after oral administration.

Dosage and Administrations

Bigmet is given by mouth in the treatment of type 2 diabetes mellitus. Initial dosage is 500 mg two or three times daily or 850 mg once or twice daily with or after meals, gradually increased if necessary to 2 to 3 g daily; doses above 2 g daily are associated with an increased incidence of gastrointestinal adverse effects.

Contra-indications

Metformin hydrochloride is contraindicated in hepatic or renal impairment (withdraw if renal impaiment suspected), predisposition to lactic acidosis, heart failure, severe infection or trauma, dehydration, alcohol dependence, pregnancy, breast feeding.

Adverse reactions

Anorexia, nausea, vomiting, diarrhea (usually transient), lactic acidosis (withdraw treatment), decreased vitamin B_{12} absorption.

Interactions

Alcohol may increase the risk of lactic acidosis as well as of hypoglycaemia.
Care should be taken if Bigmet is given concomitantly with drugs that may impair renal function.
Cimetidine reduces the renal clearance of Metformin. A reduction in Metformin dosage may be required in patients taking Metformin & Cimetidine concomitantly in order to reduce the risk of lactic acidosis.

Metformin can stimulate the action of anticoagulants.

Precautions

In case of trauma, surgery, febrile and infectious illness it may be necessary to stop treatment, substituting it with the temporary administration of insulin in order to control the diabetes adequately.

Alcohol intake: Alchohol is known to potentiate the effect of Metformin on lactate metabolism, therefore, patient should be warned against excessive alcohol intake, acute or chronic, while receiving Metformin.

Use in pregnancy

The use of Metformin is not advised.

Overdose

Overdose may cause symptoms of hypoglycaemia, which may require taking of sugar. Lactic acidosis symptoms may also occur, call a physician (see precautions).

Packs

10 x 10 Film coated tablets of 500 mg
10 x 10 Film coated tablets of 850 mg
Medicine should be kept out of the reach of children.

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RENATA LIMITED
Mirpur, Dhaka, Bangladesh