Kemin SR Tablet

Metformin Hydrochloride BP

Composition

Each sustained release tablet contains Metformin Hydrochloride BP 500 mg.

Description

Metformin Hydrochloride is a biguanide type oral anti-hyperglycemic drug used in the management of type II diabetes. It lowers both basal and postprandial plasma glucose. Mechanism of action of metformin is different from those of sulfonylureas and it does not produce hypoglycemia. Metformin decreases hepatic glucose production, decreases intestinal absorption of glucose and improves insulin sensitivity by an increase in peripheral glucose uptake and utilization. Metformin leads to fall in serum androgens, luteinizing hormone and an improvement in fertility and fibrinolysis in both obese and lean women with PCOS (Polycystic Ovary Syndrome).

Indication

Kemin-SR Tablet (Metformin Hydrochloride sustained release tablet) is used in the management of type II diabetes when diet has failed and especially if the patient is overweight. Kemin-SR, as monotherapy, is indicated as an adjunct to diet and exercise to improve glycemic control in patients with type II diabetes.

Metformin HCl can be given alone as initial therapy or can be administered in combination with oral hypoglycemic agent, insulin or glitazones when diet and exercise plus the single agent do not result in adequate glycemic control. It is also indicated in the treatment of PCOS (Polycystic Ovary Syndrome) including chronic anovulation, hirsutism and associated vascular disease in women. May also be given in combination with clomiphene citrate to enhance the ovulatory response and with oral contraceptives to have better results in hirsutism. It is advocated for IGT (Impaired Glucose Tolerance) patients to prevent progression to type II diabetes.

Dosage & Administration

Kemin-SR tablet must be swallowed whole and never be crushed or chewed. There is no fixed dosage regimen for the management of hyperglycemia in patients with type II diabetes with Kemin-SR. Dosage of Kemin-SR must be individualized on the basis of both effectiveness and tolerance, while not exceeding the maximum recommended daily dose. Kemin-SR tablet should be started at a low dose, with gradual dose escalation, to reduce gastrointestinal side-effects and to identify the minimum dose required for adequate glycemic control of the patient.

Adults: The usual starting dose of Kemin-SR is 500 mg once-daily with the evening meal. Dosage increment should be made 500 mg weekly, up to a maximum of 2000 mg once-daily with the evening meal. If glycemic control is not achieved on Kemin-SR 2000 mg once-daily, a trial of Kemin-SR 1000 mg twice daily should be considered. Patients receiving Kemin treatment may be safely switched to Kemin-SR once-daily at the same total daily dose, up to 2000 mg once-daily.

Combination treatment with sulfonylurea in adult patients:

If patients have not responded to four weeks of the maximum dose of Kemin-SR monotherapy, consideration should be given to gradual addition of an oral sulfonylurea while continuing Kemin-SR at the maximum dose, even if prior primary or secondary failure to a sulfonylurea has occurred.

Combination treatment with insulin in adult patients:

Kemin SR therapy should be initiated at 500 mg once daily in patients on insulin therapy. For patients not responding adequately, the dose of Kemin-SR should be increased by 500 mg after approximately one week and by 500 mg every week thereafter until adequate glycemic control is achieved. It is recommended that the insulin dose should be decreased by 10% to 25% when fasting plasma glucose concentration decreases to less than 120 mg/dl in patients receiving concomitant insulin and Kemin-SR therapy.

In PCOS, Kemin-SR Tablet 500 mg to 2 gm once-daily with the evening meal.

Contraindication

Individual hypersensitivity to metformin, renal & hepatic impairment, predisposition to lactic acidosis, heart failure, recent myocardial infarction, severe infection or trauma, dehydration, alcohol dependence and in acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma. Metformin sustained release tablet should be temporally 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.

Side-Effects:

Metformin is normally well tolerated but minor gastro-intestinal disturbances including diarrhea, nausea, vomiting, flatulence, indigestion, abdominal discomfort, abdominal bloating & anorexia sometimes occur which can often be avoided by taking the drug with or after food. It may induce malabsorption of vitamin B_{12}, folic acid & elevated liver enzymes. Other side-effects including asthenia, headache & rarely lactic acidosis. It is important that metformin treatment is not abandoned at the first sign of intolerance. These symptoms are generally transient and resolve spontaneously during continued treatment.

Precautions and Warning:

Metformin Hydrochloride therapy should be temporarily suspended for any surgical procedure except minor procedures not associated with restricted intake of food and fluids until the patients oral intake has resumed and renal function has been evaluated as normal.

In the event of severe trauma, injuries, infectious diseases & high fever and surgery, it may be necessary to administer insulin to maintain adequate metabolic control. Patients receiving continuous therapy should have an annual estimation of vitamin B_{12} level.

Patients should be advised to discontinue metformin immediately and to promptly notify their physician if unexplained hyperventilation, myalgia, malaise, unusual somnolence, or other nonspecific symptoms occur.

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:

Pregnancy Category B. Most experts recommended that insulin be used during pregnancy to maintain blood glucose levels as close to normal as possible. Metformin sustained release tablets should not be used during pregnancy unless clearly needed.

Use in Lactating Mother:

As the potential for hypoglycemia in nursing infants 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. If metformin is discontinued and if diet alone is inadequate for controlling blood glucose, administering insulin should be considered.

Pediatric Use:
Safety and effectiveness of metformin immediate release tablet for the treatment of type II diabetes have been established in pediatric patients' age 10 to 16 years (studies have not been conducted in pediatric patients below the age of 10 years). Sustained release metformin is not recommended for children.

Geriatric use:
Metformin sustained release tablet should only be used in patients with normal renal function.
As aging is associated with reduced renal function, metformin sustained release tablet should be used with caution as age increases. Care should be taken in dose selection and should be based on careful and regular monitoring of renal function. Generally, elderly patients should not be titrated to maximum dose of metformin.

Drug Interaction:
Patients receiving continuous metformin therapy showed a reduction in serum Vitamin B_{12} levels. Concomitant therapy of Kemin-SR with a sulphonylurea or insulin may cause hypoglycemia. Reduced renal clearance of metformin has been reported during cimetidine therapy. It may enhance the effects of anti-coagulants.

Nifedipine appears to enhance the absorption of metformin but the later has minimal effects on nifedipine, thiazides, corticosteroids, phenothiazines, thyroid products, estrogen, oral contraceptives, phenytoin, nicotinic acid, sympathomimetics, calcium channel blockers and isoniazid tend to produce hyperglycemia and may lead to loss of glycemic control.

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 by competing for common renal tubular transport systems.

Overdose:
Hypoglycemia has not been reported even with ingestion of up to 85 grams of Metformin HCl, 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 in cool and dry place, away from light. Keep out of the reach of children.

How Supplied:
Each box contains 5x10`s tablets in blister packs.

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Manufactured by:
Kemiko Pharmaceuticals Ltd.
Bangladesh