Comet™

Metformin Hydrochloride

COMPOSITION

Comet™ **500**: Each film coated tablet contains Metformin Hydrochloride BP 500 mg. **Comet**™ **750**: Each film coated tablet contains Metformin Hydrochloride BP 750 mg. **Comet**™ **850**: Each film coated tablet contains Metformin Hydrochloride BP 850 mg. **Comet**™ **1 gm**: Each film coated tablet contains Metformin Hydrochloride BP 1 gm. **Comet**™ **XR 500**: Each extended release tablet contains Metformin Hydrochloride BP 500 mg. **Comet**™ **XR 1 gm**: Each extended release tablet contains Metformin Hydrochloride BP 1 gm.

PHARMACOLOGY

Metformin is an antihyperglycemic agent that improves glucose tolerance in patients with type 2 diabetes, lowering both basal and postprandial plasma glucose. Metformin decreases hepatic glucose production, decreases intestinal absorption of glucose, and improves insulin sensitivity by increasing peripheral glucose uptake and utilization. Unlike sulfonylureas, Metformin does not produce hypoglycemia in either patients with type 2 diabetes or normal subjects and does not cause hyperinsulinemia.

INDICATION AND USAGE

Comet™ (Metformin Hydrochloride tablet) is indicated as an adjunct to diet and exercise to improve glycemic control in children and adults with type 2 diabetes mellitus.
Comet™ XR (Metformin Hydrochloride extended release tablet) is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

DOSAGE AND ADMINISTRATION

Dosage of **Comet**™ or **Comet**™ **XR** must be individualized on the basis of both effectiveness and tolerance, while not exceeding the maximum recommended daily dose. The maximum recommended daily dose of **Comet**™ is 2550 mg in adults and 2000 mg in pediatric patients (10-16 years of age); the maximum recommended daily dose of **Comet**™ **XR** in adults is 2000 mg. **Comet**™ should be given in divided doses with meals while **Comet**™ **XR** should generally be given once daily with the evening meal. **Comet**™ **XR** tablet must be swallowed whole and never be crushed or chewed. **Comet**™ or **Comet**™ **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

a) *Adults*: The usual starting dose of **Comet**™ 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. Doses above 2000 mg may be better tolerated given three times a day with meals. The usual starting dose of **Comet**™ **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 once daily with the evening meal. If glycemic control is not achieved on **Comet**™ **XR** 2000 mg once daily, a trial of **Comet**™ **XR** 1000 mg twice daily should be considered. Patients receiving **Comet**™ treatment may be safely switched to **Comet**™ **XR** once daily at the same total daily dose, up to 2000 mg once daily.

b) *Pediatrics*: The usual starting dose of **Comet**™ 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 **Comet**™ in pediatric patients below 10 years have not been established.

USE IN PREGNANCY

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

USE IN NURSING MOTHERS

Because the potential for hypoglycemia in nursing infants may 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.

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. In patients with advanced age, Metformin should be carefully titrated to establish the minimum dose for adequate glycemic effect, because aging is associated with reduced renal function.

CONTRAINDICATION

Metformin is contraindicated in patients with:
1. Renal disease or renal dysfunction (e.g., as suggested by serum creatinine levels > 1.5 mg/dL [males], > 1.4 mg/dL [females] or abnormal creatinine clearance).
2. Known hypersensitivity to Metformin hydrochloride. 3. Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma.

ADVERSE EFFECTS

Diarrhea, nausea, vomiting, flatulence, asthenia, indigestion, abdominal discomfort, headache etc.

WARNINGS

Lactic acidosis can occur due to Metformin accumulation during treatment with Metformin. The reported incidence of lactic acidosis in patients receiving Metformin is very low.

DRUG INTERACTION

No information is available about the interaction of Metformin and furosemide when co-administered chronically. Nifedipine appears to enhance the absorption of Metformin. Metformin had minimal effects on nifedipine. 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. Metformin had no effect on cimetidine pharmacokinetics. Certain drugs tend to produce hyperglycemia and may lead to loss of glycemic control. These drugs include the thiazides and other diuretics, corticosteroids, phenothiazines, thyroid products, estrogens, oral contraceptives, phenytoin, nicotinic acid, sympathomimetics, calcium channel blocking drugs, and isoniazid.

STORAGE

Store at cool and dry place and keep away from light. Keep out of reach of children.

HOW SUPPLIED

Comet™ **500**: Each box contains 100 tablets in blister pack. **Comet**™ **750**: Each box contains 60 tablets in blister pack. **Comet**™ 850: Each box contains 50 tablets in blister pack. **Comet**™ **1 gm:** Each box contains 30 tablets in blister pack. **Comet**™ **XR 500**: Each box contains 50 tablets in blister pack. **Comet**™ **XR 1 gm**: Each box contains 30 tablets in blister pack.

Manufactured by :

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