

Film Coated Tablets

Comet

Metformin HCl B.P.

فلم کوئٹہ گولیاں
کوئٹہ
میٹ فارمن ہائیڈروکلورائیڈ پی

Composition:

Each film coated tablet contains:
Metformin HCl B.P.500mg / 850mg
B.P. Specs.

Mechanism of Action:

Metformin is an antihyperglycemic agent which improves glucose tolerance in patients with type 2 diabetes, lowering both basal and postprandial plasma glucose. Its pharmacologic mechanisms of action are different from other classes of oral antihyperglycemic agents. Metformin decreases hepatic glucose production, decreases intestinal absorption of glucose, and improves insulin sensitivity by increasing peripheral glucose uptake and utilization. Unlike sulphonylureas, Metformin does not produce hypoglycemia in either patients with type 2 diabetes or normal subjects (except in special circumstances)

Indications:

1. Non-insulin dependent diabetes when diet has failed and especially when the patient is overweight. It can be given alone as initial therapy or in combination with a sulphonylurea.
2. As an adjuvant to insulin in patients with insulin dependent diabetes whose symptoms are poorly controlled.

Dosage and Administration:

Initially 1500mg to 1700mg daily in divided doses. 1 tablet of Comet 500mg three times or 2 tablets of Comet 850 mg two times with or after food. Good diabetic control may be achieved within few days but in few cases may be delayed for two weeks. If control is incomplete a cautious increase to 3gm daily maximum is justified. Once adequate control has been obtained it may be possible to reduce the dosage.

Combination with insulin:

Metformin and insulin may be used in combination therapy to achieve better blood glucose control. Metformin is given at the usual starting dose of 1 tablet **Comet** 500mg 2 & 3 times daily, while insulin dosage is adjusted on the basis of blood glucose measurement.

Child hood diabetes:

Metformin is the only oral antidiabetic approved for this indication by FDA and EMEA for children above 10 years of age. The maximum dose of Metformin for this indication is 2000mg daily.

Elderly: Metformin is indicated in elderly, but not when renal functions are reduced.

Contra-indications:

Metformin is contra-indicated in patients with the following conditions:
Known hypersensitivity to the drug, diabetic coma, ketoacidosis infarction, history of states associated with lactic acidosis or hypoxemia and alcoholism.

Use during pregnancy and lactation:

Treatment should be stopped 2-3 days before surgery or clinical investigations such as intravenous urography and intravenous angiography - it should be restarted after control of renal functions has been regained.

Special warnings and precautions:

The use of Comet (Metformin) is not advised in conditions which may cause dehydration or in serious infection or trauma. Metformin should be used with caution in patients with decreased renal functions. Since Metformin is readily excreted by the kidneys, so regular monitoring is advised. Vitamin B12 levels should be estimated annually during concomitant therapy with a sulphonylurea. Blood glucose should be monitored.

Side-effects:

Comet (Metformin) is normally well tolerated, although as with all drugs, unwanted side-effects do sometimes occur.

Gastrointestinal disturbances sometime occur and can often be avoided by taking metformin with or after food but a temporary lowering of the dose may be needed. In patients with a metabolic acidosis lacking evidence of ketoacidosis lactic acidosis should be suspected, metformin therapy should be stopped and patient must be treated in the hospital.

Interactions:

Metformin may interact with cimetidine and anticoagulants

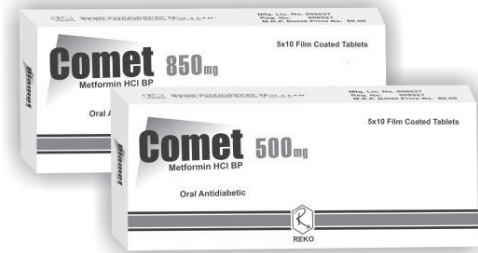
Overdosage:

Hypoglycaemia can occur when Comet (Metformin) is given with a sulphonylurea, insulin or alcohol. Lactic acidosis which may occur through excessive dosage or due to accumulation is a medical emergency, and the patients should be hospitalised. Intensive therapy should be directed at correcting fluid loss metabolic disturbance.

How Supplied:

White tablets in blister pack
as follows:

Comet 500mg 5x10's
Comet 850mg 5x10's



Manufactured by:
REKO PHARMACAL (Pvt.) LTD.
13-km, Multan Road, Lahore-Pakistan
www.rekopharmacal.com

