

# Combimet®



Glipizide and Metformin Hydrochloride  
Tablet

## Presentation

Each Combimet® tablet contains 2.5 mg Glipizide BP with 250 mg Metformin Hydrochloride BP, each Combimet® Plus tablet contains 2.5 mg Glipizide BP with 500 mg Metformin Hydrochloride BP and each Combimet® DS tablet contains 5 mg Glipizide BP with 500 mg Metformin Hydrochloride BP.

## Description

Combimet® combines Glipizide and Metformin Hydrochloride, two antihyperglycemic agents with complementary mechanisms of action, to improve glycemic control in patients with type 2 diabetes. Glipizide appears to lower blood glucose acutely by stimulating the release of insulin from the pancreas, an effect dependent upon functioning beta cells in the pancreatic islets.

Metformin Hydrochloride is an antihyperglycemic agent that improves glucose tolerance in patients with type 2 diabetes, lowering both basal and postprandial plasma glucose. Metformin Hydrochloride decreases hepatic glucose production, decreases intestinal absorption of glucose and improves insulin sensitivity by increasing peripheral glucose uptake and utilization.

## Indication

Combimet® is indicated as initial therapy, as an adjunct to diet and exercise, to improve glycemic control in patients with type 2 diabetes whose hyperglycemia cannot be satisfactorily managed with diet and exercise alone. It is also indicated as second line therapy when diet, exercise and initial treatment with Metformin or Glipizide do not result in adequate glycemic control in patients with type 2 diabetes.

## Dosage and Administration

Initial therapy: For patients with type 2 diabetes whose hyperglycemia can not be satisfactorily managed with diet and exercise alone, the recommended starting dose of Combimet® is 2.5 mg/250 mg once daily with meal. In clinical trials of Combimet® as initial therapy, there was no experience with total daily doses greater than 10 mg/2000 mg once daily with meal.

## Second Line Therapy

For patients not adequately controlled on either Glipizide or Metformin alone, the recommended starting dose of Combimet® is 2.5 mg/500 mg or 5 mg/500 mg twice daily with the morning and evening meals. The daily dose should be titrated in increments of no more than 5 mg/500 mg up to the minimum effective dose to achieve adequate control of blood glucose or to a maximum dose of 20 mg/2000 mg.

## Contraindication

Severe hepatic or renal dysfunction, congestive heart failure requiring pharmacologic treatment, known hypersensitivity to Glipizide or Metformin Hydrochloride and acute or chronic metabolic acidosis, including diabetes acidosis, with or without coma. Combimet® is usually not advised during pregnancy & lactation and for pediatric use.

## Side Effects

The most common side effects of Combimet® are normally minor ones such as diarrhea, nausea/vomiting, dizziness, headache and abdominal pain which usually occur during the first few weeks of therapy.

## Precautions

In the event of severe trauma, injuries, infectious diseases, severe renal & hepatic impairment, myocardial infarction, coma, high fever & surgery, it may be necessary to give insulin to maintain adequate metabolic control. Patients receiving continuous therapy should have an annual estimation of vitamin B<sub>12</sub> level.

## Drug Interactions

The hypoglycemic action of Glipizide component may be potentiated by Aspirin & phenylbutazone, sulfonamides, chloramphenicol, coumarins, probenecid, monoamino oxidase inhibitors, beta-adrenergic blocking agents, H<sub>2</sub> antagonists and oral antifungal agents like miconazole and Fluconazole. Metformin may enhance the effects of anticoagulants, thiazides, corticosteroids, thyroid hormones, estrogens, oral contraceptives, phenytoin, nicotinic acid, sympathomimetics, calcium channel blockers and isoniazid tend to produce hyperglycemia and may lead to loss of glycemic control.

## Commercial Pack

Combimet® tablet: Each box contains 10x10's tablets in blister strips.

Combimet® Plus tablet: Each box contains 6x10's tablets in blister strips.

Combimet®DS tablet: Each box contains 6x10's tablets in blister strips.



Manufactured by

**BEXIMCO PHARMACEUTICALS LTD.**

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