

# Sensimet™

## Rosiglitazone + Metformin HCl

### COMPOSITION

**Sensimet™ 1:** Each film coated tablet contains Rosiglitazone 1 mg as Rosiglitazone maleate INN and Metformin Hydrochloride BP 500 mg.

**Sensimet™ 2:** Each film coated tablet contains Rosiglitazone 2 mg as Rosiglitazone maleate INN and Metformin Hydrochloride BP 500 mg.

### PHARMACOLOGY

**Sensimet™** (Rosiglitazone maleate and Metformin Hydrochloride) combines two antidiabetic agents with different mechanisms of action to improve glycemic control in patients with type 2 diabetes : Rosiglitazone, a member of the thiazolidinedione class and Metformin, a member of the biguanide class. Rosiglitazone decreases insulin resistance in the periphery and in the liver resulting in increased insulin-dependent glucose disposal and decreased hepatic glucose output. Rosiglitazone is a potent and highly selective agonist for peroxisome proliferator-activated receptor-gamma (PPAR- $\gamma$ ). Activation of PPAR- $\gamma$  nuclear receptors modulates the transcription of a number of insulin responsive genes involved in the control of glucose and lipid metabolism.

Metformin hydrochloride 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.

### INDICATION AND USAGE

**Sensimet™** is indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus who are already treated with combination of Rosiglitazone and Metformin or who are not adequately controlled on Metformin alone.

### DOSAGE AND ADMINISTRATION

The dosage of antidiabetic therapy with **Sensimet™** should be individualized on the basis of effectiveness and tolerability.

**Sensimet™** is generally given in divided doses with meals, with gradual dose escalation. The recommended starting dose of **Sensimet™** is 2 mg/500mg administered once or twice daily. The dose of **Sensimet™** may be increased in increments of 2 mg/500 mg per day to a maximum of 8 mg/2,000 mg per day given in divided doses if patients are not adequately controlled after 4 weeks.

For patients inadequately controlled on Metformin monotherapy: The usual starting dose of **Sensimet™** is 4 mg Rosiglitazone (total daily dose) plus the dose of Metformin already being taken.

For patients inadequately controlled on Rosiglitazone monotherapy: The usual starting dose of **Sensimet™** is 1,000 mg Metformin (total daily dose) plus the dose of Rosiglitazone already being taken.

### CONTRAINDICATION

Combination of Rosiglitazone and Metformin tablets are contraindicated in patients with:

- Renal disease or renal dysfunction which may also result from conditions such as cardiovascular collapse (shock), acute myocardial infarction and septicemia.
- Congestive heart failure requiring pharmacologic treatment.
- Known hypersensitivity to Rosiglitazone maleate or Metformin hydrochloride.
- Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma. Diabetic ketoacidosis should be treated with insulin.

### ADVERSE REACTIONS

The incidence of adverse events reported are upper respiratory tract infection, headache, back pain, hyperglycemia, fatigue, sinusitis, diarrhea and hypoglycemia. Nausea, vomiting, flatulence, asthenia, indigestion, abdominal discomfort, headache etc are reported with Metformin treated patients.

### DRUG INTERACTIONS

Although drug interactions with cationic drugs (e.g., amiloride, digoxin, morphine, procainamide, quinidine, quinine, ranitidine, triamterene, trimethoprim and vancomycin) remain theoretical (except for cimetidine), careful patient monitoring and dose adjustment of combination of Rosiglitazone and Metformin and/or the interfering drug is recommended in patients who are taking cationic medications that are excreted via the proximal renal tubular secretory system.

When drugs that produce hyperglycemia which may lead to loss of glycemic control are administered to a patient receiving combination of Rosiglitazone and Metformin, the patient should be closely observed to maintain adequate glycemic control.

### USE IN PREGNANCY AND LACTATION

Pregnancy Category C : Combination of Rosiglitazone and Metformin should not be used during pregnancy unless the potential benefit justifies the potential risk to the fetus. It is not known whether Rosiglitazone and/or Metformin are excreted in human milk. Because many drugs are excreted in human milk, combination of Rosiglitazone and Metformin should not be administered to a nursing woman.

### STORAGE

Store in a cool and dry place. Protect from light and moisture.

### HOW SUPPLIED

**Sensimet™ 1:** Each box contains 30's in blister pack.

**Sensimet™ 2:** Each box contains 30's in blister pack.

Manufactured by :



TM Trade Mark.