

### Composition:

Sensulin ® 2 : Each film coated tablet contains  
Rosiglitazone maleate INN.

Sensulin ® 4 : Each film coated tablet contains  
Rosiglitazone maleate INN.

### Pharmacology:

Rosiglitazone, a member of the thiazolidinedione class, improves glycemic control by improving insulin sensitivity. It is a potent agonist for the peroxisome proliferator-activated receptor (PPAR) in humans, PPAR receptors are found in key target tissues, skeletal muscle, and liver. Activation of PPAR leads to transcription of insulin-responsive genes involved in glucose transport, and utilization. In addition, PPAR- $\alpha$  is involved in regulation of fatty acid metabolism. Pharmacological studies show that Rosiglitazone improves sensitivity to insulin, and inhibits hepatic gluconeogenesis. Rosiglitazone is not related to the sulfonylureas, the biguanides, or the

### Indication and Usage:

Sensulin ® (Rosiglitazone) is indicated as an adjunct to diet and exercise for glycemic control in patients with type 2 diabetes.

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Combination therapy: When Rosiglitazone is added to existing therapy, the dose(s) of the agent(s) can be continued upon

Sulfonylurea: When used in combination with Rosiglitazone is 4 mg administered as either a single dose once daily or in divided doses twice daily. If patients report hypoglycemia, the dose should be decreased.

Metformin: The usual starting dose of Rosiglitazone is 4 mg administered as either a single dose once daily or in divided doses twice daily. It is unlikely that the dose of metformin will require adjustment in combination therapy with Rosiglitazone.

Insulin: For patients stabilized on insulin, the usual starting dose of Rosiglitazone is 4 mg administered as either a single dose once daily or in divided doses twice daily. Upon initiation of therapy with Rosiglitazone, Rosiglitazone doses greater than 4 mg daily are not currently indicated. It is recommended that the dose of insulin be adjusted if the patient reports hypoglycemia or if FPG is < 70 mg/dL. Further adjustments should be individualized based on patient response.

Sulfonylurea plus metformin: The usual starting dose of Rosiglitazone is 4 mg administered as either a single dose once daily or in divided doses twice daily. If patients

### Precaution:

Due to its mechanism of action, Rosiglitazone increases endogenous insulin. Therefore, Rosiglitazone should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. Rosiglitazone, like other thiazolidinediones, alone or in combination with other drugs, may cause fluid retention, which may exacerbate or lead to heart failure. Signs and symptoms of heart failure. In combination with other drugs, also increase the risk of other cardiovascular events. Rosiglitazone should be discontinued if any deterioration in cardiac status is observed. Use with caution in patients with edema. Liver enzyme levels should be monitored at initiation of therapy with Rosiglitazone in all patients. Rosiglitazone should be initiated in patients with increased baseline liver enzyme levels (upper limit of normal).

### Drug Interaction:

In vitro drug metabolism studies suggest that Rosiglitazone is not a major P450 enzyme substrate. Rosiglitazone may be needed when gemfibrozil is required when administered with rifampin. Rosiglitazone has no relevant effect on the pharmacokinetics of nifedipine.

### Use in Pregnancy & Lactation:

There are no adequate and well controlled studies in pregnant women.