

ROSILON *Film Coated Tablets*

Rosiglitazone Maleate

Oral Antidiabetic Agent

Composition:

Each tablet contains:

- Rosiglitazone Maleate 4mg.

Properties:

Rosiglitazone Maleate is a thiazolidinedione (TZDs) oral antidiabetic agent, acts primarily by increasing insulin sensitivity. It improves glycemic control while reducing circulating insulin levels. It improves sensitivity to insulin in skeletal muscle and adipose tissue and inhibits hepatic gluconeogenesis.

Rosiglitazone is well absorbed from the gastrointestinal tract following oral dosing. Peak plasma concentrations are achieved within 1 hour and the bioavailability is 99%. It is 99.8% bound to plasma proteins. It is extensively metabolized by specific liver enzyme. Elimination half life is 3-4 hours through the urine and faeces.

Indications & Usage:

- **ROSILON is indicated as oral monotherapy as adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus (non-insulin-dependent diabetes mellitus).**
- **ROSILON is also indicated for use in combination with a sulfonylurea, metformin,**



or insulin when diet, exercise, and a single agent do not result in adequate glycemic control.

Usage During Pregnancy & Lactation:

ROSILON should not be used during pregnancy or lactation.

Dosage & Administration:

" ROSILON may be taken with or without food "

- Monotherapy:

- The recommended dose of ROSILON is 4 mg as a single daily dose or in divided doses twice daily.

- For patients who respond inadequately following 8 to 12 weeks of treatment, the dose may be increased to 8 mg daily as a single daily dose or in divided doses twice daily.

- Combination Therapy:

With Sulfonylurea or Metformin:

combination with sulfonylurea or metformin, the recommended dose of ROSILON is 4 mg administered as either a single dose once daily or in divided doses twice daily.

" If patients report hypoglycemia, the dose of the sulfonylurea should be decreased, and the dose of metformin will require adjustment "

With Insulin:

the insulin dose should be continued upon initiation of therapy with ROSILON.

ROSILON should be dosed at 4 mg daily.

Doses of ROSILON greater than 4 mg daily in combination with insulin are not currently indicated. It is recommended that the insulin dose be decreased by 10 % to 25 % if the patient reports hypoglycemia.

*** Maximum recommended dose : The dose of ROSILON should not exceed 8 mg daily, as a single dose or divided twice daily.**

Packing:

20 tablets (2 strips X 10 tablets).