



**Comet<sup>®</sup>**

Metformin  
**Oral Antidiabetic**

### COMPOSITION

Comet<sup>®</sup> 500 : Each film coated tablet contains Metformin Hydrochloride BP 500 mg.

Comet<sup>®</sup> 850 : Each film coated tablet contains Metformin Hydrochloride BP 850 mg.

Comet XR<sup>®</sup> 500: Each extended release tablet contains Metformin Hydrochloride BP 500 mg.

### INDICATIONS AND USE

Comet<sup>®</sup> (metformin hydrochloride tablets) and Comet XR<sup>®</sup> (metformin hydrochloride extended release tablets) are oral antihyperglycemic drugs used in the management of type 2 diabetes.

### DOSAGE AND ADMINISTRATION

Comet<sup>®</sup> should be given in divided doses with meals while Comet XR<sup>®</sup> should generally be given once daily with the evening meal. The maximum recommended daily dose of Comet<sup>®</sup> is 2550 mg in adults and 2000 mg in pediatric patients (10-16 years of age); the maximum recommended daily dose of Comet XR<sup>®</sup> in adults is 2000 mg. Comet XR<sup>®</sup> tablets must be swallowed whole and never be crushed or chewed. Recommended Dosing Schedule -

*Adults:* The usual starting dose of Comet<sup>®</sup> (metformin hydrochloride tablets) is 500 mg twice a day or 850 mg once a day, given with meals. Dosage increases should be made in increments of 500 mg weekly or 850 mg every 2 weeks, up to a total of 2000 mg per day, given in divided doses. Patients can also be titrated from 500 mg twice a day to 850 mg twice a day after 2 weeks. For those patients requiring additional glycemic control, Comet<sup>®</sup> may be given to a maximum daily dose of 2550 mg per day. Doses above 2000 mg may be better tolerated given three times a day with meals. The usual starting dose of Comet XR<sup>®</sup> (metformin hydrochloride extended-release tablets) is 500 mg once daily with the evening meal. Dosage increases should be made in increments of 500 mg weekly, up to a maximum of 2000 mg once daily with the evening meal. If glycemic control is not achieved on Comet XR<sup>®</sup> 2000 mg once daily, a trial of Comet XR<sup>®</sup> 1000 mg twice daily should be considered. If higher doses of metformin are required, Comet<sup>®</sup> should be used at total daily doses up to 2550 mg administered in divided daily doses, as described above. Patients receiving Comet<sup>®</sup> treatment may

ORAL ANTI-DIABETIC PREPARATIONS

## Comet®

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be safely switched to Comet XR® once daily at the same total daily dose, up to 2000 mg once daily.

*Pediatrics:* The usual starting dose of Comet® is 500 mg twice a day, given with meals. Dosage increases should be made in increments of 500 mg weekly up to a maximum of 2000 mg per day, given in divided doses. Safety and effectiveness of Comet® in pediatric patients below 10 years have not been established.

*Combination treatment with sulfonylurea in Adult Patients:* Comet® or Comet XR® at the maximum dose + gradual addition of a sulfonylurea.

*Combination treatment with insulin in Adult Patients:* Insulin + Comet® or Comet XR® (starting with 500 mg once daily).

*Specific Patient Populations:* Not recommended in pregnant and breastfeeding mothers. Metformin immediate release tablets are not recommended below the age of 10 years while Metformin extended release tablets are not recommended below the age of 17.

*Geriatric Use:* Metformin immediate and extended release tablets should only be used in patients with normal renal function. Care should be taken in dose selection and should be based on careful and regular monitoring of renal function.

### **SIDE EFFECT**

Diarrhea, nausea/vomiting, flatulence, abdominal discomfort, headache, etc.

### **HOW SUPPLIED**

Comet® 500 : Box containing 10 x 10 tablets in blister pack.

Comet® 850 : Box containing 5 x 10 tablets in blister pack.

Comet XR® 500 : Box containing 5 x 10 tablets in blister pack.

