Minibet™

Ciprofibrate EP

COMPOSITION

Minibet™ Tablet: Each tablet contains Ciprofibrate EP 100 mg.

PHARMACOLOGY

Ciprofibrate reduces both LDL & VLDL and hence the levels of triglyceride and cholesterol associated with these lipoprotein fractions. It also increases levels of HDL cholesterol. Ciprofibrate is effective in the treatment of hyperlipidemia associated with high plasma concentrations of LDL and VLDL. There is evidence that treatment with fibrates may reduce coronary heart disease events.

INDICATION

Ciprofibrate is indicated as an adjunct to diet, exercise and weight reduction for the following:

- Treatment of severe hypertriglyceridemia with or without low HDL cholesterol.
- Mixed hyperlipidemia when a statin is contraindicated or not tolerated.

DOSAGE & ADMINISTRATION

Adults: The recommended dose is one **Minibet**™ Tablet (Ciprofibrate 100mg) per day. This dose should not be exceeded.

Patients with renal insufficiency: In moderate renal impairment (creatinine clearance 30-80 ml/min/1.73m^2) it is recommended that dosage be reduced to one tablet every other day. Patients should be carefully monitored. Ciprofibrate should not be used in severe renal impairment (creatinine clearance <30 ml/min/1.73m^2).

Patients with hepatic insufficiency: Use with caution in patients with impaired hepatic function. Ciprofibrate treatment should be discontinued in case of increased AST and ALT levels to more than 3 times the upper limit of normal or if cholestatic liver injury is evidenced.

Elderly: As for adults but precautions should be taken for Age more than 70 years.

Paediatric population: Not recommended since safety and efficacy in children has not been established.

CONTRAINDICATION

- Hypersensitivity to the active substance or to any of the excipients
- Severe hepatic impairment
- Severe renal impairment (creatinine clearance <30 ml/min/1.73m^2)
- Pregnancy and lactation or when pregnancy is suspected
- Concurrent use with another fibrate

PRECAUTION

Special warnings: Patients with rare hereditary problems of galactose intolerance, lactose deficiency or glucose-galactose malabsorption should not take this medicine.

Myalgia/myopathy: Patients should be advised to report unexplained muscle pain, tenderness or weakness immediately.

Patients with impaired hepatic function: Periodic hepatic function tests are recommended (every 3 months for the first 12 months of treatment). Ciprofibrate treatment should be discontinued in case of increased AST and ALT levels to more than 3 times the upper limit of normal or if cholestatic liver injury is evidenced.

SIDE EFFECTS

Headache, Dizziness, Somnolence, Vertigo, Nausea, Vomiting, Diarrhoea, Dyspepsia, Abdominal pain, Rash, Alopecia, Myalgia, Fatigue.

DRUG INTERACTION

Other fibrates & HMG CoA reductase inhibitors: As Risk of myopathy, rhabdomyolysis and myoglobinuria may be increased if Ciprofibrate is used in combination with other fibrates and HMG CoA reductase inhibitors.

Oral anticoagulant therapy: Caution should be exercised when Ciprofibrate is taken with oral anticoagulants. Concomitant oral anticoagulant therapy should be given at reduced dosage and adjusted according to INR.

USE IN PREGNANCY AND LACTATION

Use in Pregnancy: There is no evidence that Ciprofibrate is teratogenic but signs of toxicity at high doses were observed in teratogenicty tests in animals. As there are no data on its use in human pregnancy, Ciprofibrate is contraindicated during pregnancy.

Lactation: As there are no data on its use in lactation, Ciprofibrate is contraindicated in nursing mothers.

STORAGE

Store below 30°C. Protect from light and moisture. Keep the medicine out of reach of children.

HOW SUPPLIED

Minibet™ Tablet: Each box contains 30 tablets in blister pack.

Manufactured by

SQUARE
PHARMACEUTICALS LTD.
Salgaria, Pabna, Bangladesh