ZIVENT MR

TRIMETAZIDINE HYDROCLORIDE BP

Compositions:
Zivent MR Tablet: Each modified release tablet contains Trimetazidine Hydrochloride BP 35 mg.

Pharmacology:
Trimetazidine Hydrochloride has been proven to exert antianginal properties due to its specific metabolic mechanism of action. Trimetazidine Hydrochloride reduces the metabolic damage caused during ischemia, by acting on a critical step in cardiac metabolism: fatty acid oxidation. This is made possible by selective inhibition of an enzyme of fatty acid oxidation: the long-chain 3-ketoacyl CoA thiolase (3-KAT). This inhibition results in reduction in fatty acid oxidation & stimulation of glucose oxidation. Thus, the coupling of glycolysis with glucose oxidation is improved, and ATP production is further increased, while the deleterious consequences of acidosis and of Ca2+ overload are limited.

Dosage And Administration:
Adult: One tablet at mealtimes in the morning and evening. Elderly and Renal Impairment: Elderly patients may have increased Trimetazidine exposure due to age-related decrease in renal function. In patients with moderate renal impairment (creatinine clearance 30-60 ml/min), the recommended dose is 1 tablet of 35 mg in the morning during breakfast. Dose titration in elderly patients should be exercised with caution. Paediatric: The safety and efficacy of Trimetazidine in children aged below 18 years have not been established.

Contraindications:
Hypersensitivity to Trimetazidine Hydrochloride.

Warning And Precaution:
This drug is not a curative treatment for angina attacks, nor is it indicated as an initial treatment for unstable angina, or myocardial infarction. It should not be used in the pre-hospital phase or during the first days of hospitalization. In the event of an angina attack, the coronaropathy should be reevaluated and an adaptation of the treatment considered (drug treatment and possibly revascularisation). In patients with renal failure, prescription of Trimetazidine is not recommended if the creatinine clearance is lower than 15 ml/min (in the absence of specific studies). In patients with severe hepatic failure, in the absence of specific studies, prescription of Trimetazidine is not recommended.

Side Effects:
Trimetazidine is safe and well tolerated. The most commonly side effects are gastric discomfort, nausea, headache and vertigo. However, the side effects are mild and non-specific.

Use in Pregnancy and Lactation:
Pregnancy: Studies in animals have not demonstrated a teratogenic effect. However, in the absence of clinical data and for safety reasons, prescription should be avoided during pregnancy. Breast feeding: In the absence of data, breastfeeding is not recommended during treatment.

Drug Interaction:
The clinical studies of Trimetazidine showed no evidence of interactions with other drugs.

Overdosage:
Very limited information is available on Trimetazidine overdose. Treatment should be symptomatic.

Storage:
Store in a cool (below 30°C) and dry place protected from light and moisture. Keep out of the reach of children.

Packing:
Zivent MR Tablet: Each box contains 5 x 10's tablet in Alu-Alu blister pack.

Manufactured By:
The IBN SINA Pharmaceutical Industry PLC.
Shafipur, Gazipur, Bangladesh.