METAZINE TABLET 20MG

DESCRIPTION:
A round tablet, scored on one side and with marking 'DUO 3' on the scored side and 'DUO 4' on the other side.

COMPOSITION:
Each tablet contains Trimetazidine Dihydrochloride 20 mg.

PHARMACODYNAMICS:
Trimetazidine restores the energetic activity and the operation of the ionic pump in the membrane of the ischaemic cell, especially at the myocardial level. In patients suffering from angina pectoris, Metazine increases coronary reserve, prevents sudden rises in blood pressure and reduces the frequency of attacks.

PHARMACOKINETICS:
Absorption
Following oral administration blood levels reach a peak in 2 - 3 hours and then decrease gradually with terminal half-life of about 6 hours. The bioavailability of orally administered trimetazidine is approximately 90%. Food intake does not modify absorption.
Metabolism
The major route of elimination is urinary, with about 60% of the administered dose being eliminated in the unchanged form. The rest is metabolized. Little is known of the properties of the metabolites, which are however only present in weak concentrations.
Plasma Protein Binding
Approximately 16% is bound to plasma proteins, chiefly albumin.

INDICATION:
Trimetazidine is indicated in adults as add-on therapy for the symptomatic treatment of patients with stable angina pectoris who are inadequately controlled by or intolerant to first-line antianginal therapies.

RECOMMENDED DOSAGE:
The dose is one tablet of 20mg of trimetazidine three times a day during meals.
The benefit of the treatment should be assessed after three months and trimetazidine should be discontinued if there is no treatment response.
Special populations
Patient with renal impairment:
In patients with moderate renal impairment (creatinine clearance [30-60] ml/min), the recommended dose is 1 tablet of 20mg twice daily i.e., one in the morning and one in the evening during meals.
Elderly patient:
Elderly patient may have increased trimetazidine exposure due to age-related decrease in renal function. In patient with moderate renal impairment (creatinine clearance [30-60] ml/min), the recommended dose is 1 tablet of 20mg twice daily, i.e., one in the morning and one in the evening during meals. Dose titration in elderly patients should be exercised with caution.

ROUTE OF ADMINISTRATION:
Oral

CONTRAINDICATIONS:
- Hypersensitivity to trimetazidine or any compounds of the product.
- Parkinson disease, parkinsonian symptoms, tremors, restless leg syndrome, and other related movement disorders
- Severe renal impairment (creatinine clearance <30ml/min)

WARNINGS & PRECAUTIONS:
Trimetazidine can cause or worsen parkinsonian symptoms (tremor, akinesia, hypertonia), which should be regularly investigated, especially in elderly patients. In doubtful cases, patients should be referred to a neurologist for appropriate investigations.
The occurrence of movement disorders such as parkinsonian symptoms, restless leg syndrome, tremors, gait instability should lead to definitive withdrawal of trimetazidine.
These cases have a low incidence and are usually reversible after treatment discontinuation. The majority of the patients recovered within 4 months after trimetazidine withdrawal. If parkinsonian symptoms persist more than 4 months after drug discontinuation, a neurologist opinion should be sought.
Falls may occur, related to gait instability or hypotension, in particular in patients taking antihypertensive treatment.
Caution should be exercised when prescribing trimetazidine to patient in whom an increased exposure is expected:
- moderate renal impairment
- elderly patient older than 75 years old.

INTERACTION WITH OTHER MEDICAMENTS:
No drug interaction has been reported.
Drug Combinations: Trimetazidine can be prescribed in conjunction with heparin, calciparine, vitamin K antagonists, lipid-lowering drugs, aspirin, β- blockers, calcium uptake inhibitors and digitaloids.
Incompatibility: None

USE IN PREGNANCY & LACTATION:
Pregnancy
There are no data for the use of trimetazidine in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. As a precautionary measure, it is preferable to avoid the use of Metazine Tablet 20mg during pregnancy.

Breast-feeding
It is unknown whether trimetazidine/metabolites are excreted in human milk. A risk to the newborns/infants cannot be excluded. Metazine Tablet 20mg should not be used during breast-feeding.

SIDE EFFECTS:
Rare cases of gastrointestinal effects such as nausea and vomiting may occur.
Nervous systems disorders:
Frequency not known: Parkinsonian symptoms (tremor, akinesia, hypertonia), gait instability, restless leg syndrome, other related movement disorders, usually reversible after treatment discontinuation.

SYMPTOMS AND TREATMENT OF OVERDOSE:
No case of overdosage has been reported. In view of high therapeutic margin, there is no risk of severe overdosage. IV overdoses may cause a drop in peripheral resistance with hypotension and hot flushes.

STORAGE CONDITIONS:
Store in dry place below 30˚C. Protect from light. Keep out of reach of children. *Jauhkan daripada kanak-kanak.*

SHELF LIFE:
Please refer to outer package.

PACK SIZE:
Blister pack of 90, 100, and 500 tablets.

PRODUCT REGISTRATION HOLDER & MANUFACTURER:
DUOPHARMA (M) SDN BHD
Lot 2599, Jalan Seruling 59 Kawasan 3,
Taman Klang Jaya, 41200 Klang, Selangor, MALAYSIA.

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