Effezidine
Country: **Philippines**
Date: 07-02-2022

97mm 97mm

234mm

TRIMETAZIDINE Hydrochloride

Rx **EFFEZIDINE**
35 mg Modified-Release Tablet
ANTI-ANGINA

FORMULATION:
Each Modified Release Tablet contains:
Trimetazidine (as Hydrochloride), BP.....35 mg

PRODUCT DESCRIPTION:
Trimetazidine (EFFEZIDINE) is a light yellow coloured, circular and biconvex tablet having a heart-shaped logo on one side and a breakline on the other side.

PHARMACOLOGY:
Trimetazidine Hydrochloride is a metabolic agent, a specific and selective inhibitor of an enzyme of the fatty acid β-oxidation: The 3-ketoacyl CoA thiolase (3-KAT). This inhibition of β-oxidation allows a recoupling of glycolysis and an increase in glucose oxidation for better energy of production under ischaemic conditions. By preserving the energy metabolism in cells exposed to hypoxia or ischaemia, Trimetazidine prevents a decrease in intracellular ATP levels, thereby ensuring the proper functioning of ionic pumps and transmembranous sodium-potassium flow while maintaining cellular homeostasis. In animals, Trimetazidine helps maintain energy metabolism in the heart and neurosensory organs during episodes of ischaemia and hypoxia; reduces intracellular acidosis and alterations in the transmembrane ion flow caused by ischaemia; decrease the migration and infiltration of polynuclear neutrophils in ischaemic and reperfused cardiac tissue. It also reduces the size or experimental infarctions; exerts this action in the absence of any direct haemodynamic effect. In man, controlled studies in angina patients have shown that Trimetazidine increase coronary flow reserve, thereby delaying the onset of exercise- induced ischaemia, starting from the 15th day of treatment; limits rapid swings in blood pressure without any significant variations in heart rate; significantly decrease the frequency of angina attacks; leads to a significant decrease in the use of nitroglycerin. In a 2-months study in patients receiving 50 mg atenolol, adding one 35 mg Trimetazidine Hydrochloride modified release tablet produced a significant increase in the time to 1-mm ST-segment depression in exercise test, when compared to a placebo, 12 hours after taking the drug.

PHARMACOKINETICS:
After oral administration maximum concentrations is found on average 5 hours after taking the tablet. Over 24 hours, the plasma concentration remains at levels ≥75% of the maximum concentration for 11 hours. Steady state is reached by the 60th hour, at the least. The pharmacokinetic characteristics of Trimetazidine Hydrochloride are not influenced by meals. The apparent distribution volume is 4.8 L/kg; protein-binding is low; in vitro measurements give value of 16. Trimetazidine Hydrochloride is eliminated primarily in the urine, mainly in the unchanged form. The elimination half-life of Trimetazidine Hydrochloride is an average of 7 hours in healthy young volunteers and 12 hours in subjects >65 years. Total clearance of Trimetazidine Hydrochloride is the result Trimetazidine Hydrochloride of the major renal clearance which is directly correlated to creatinine clearance and, to a lesser extent, to liver clearance which is reduced with age. A specific clinical study carried out in an elderly population using a dosage of 2 tabs/day taken in 2 doses, analyzed by a kinetic population method an increase in plasma exposure which does not justify a dosage alteration.

INDICATIONS:
Preventive treatment of episodes of angina. Adjuvant symptomatic treatment of vertigo and tinnitus. Adjuvant treatment of visual disorders of circulatory origin.

DRUG INTERACTIONS:
No drug interactions so far have been reported. In particular, no interactions have been reported with beta-blockers, calcium antagonists, nitrates, heparin, hypolipidaemic agents or digitalis preparation.

CONTRAINDICATIONS:
Hypersensitivity to any of the constituents of Trimetazidine Hydrochloride.
Use in lactation: Trimetazidine Hydrochloride is generally not recommended during breastfeeding.

SPECIAL PRECAUTIONS:
Trimetazidine Hydrochloride is not curative for angina attacks, not an initial treatment for unstable angina pectoris. It is not used for treatment of myocardial infarction. In the event of angina attack, physician must be informed. Tests may be required and treatment may possibly be modified. Trimetazidine Hydrochloride can aggravate or cause symptoms similar to those of Parkinson's disease (tremor, difficulty in making movements, rigidly of limbs), which should be investigated and reported to a doctor, especially in elderly patients. Falls may occur following a drop in blood pressure or a loss of balance. Ask doctor or a pharmacist for advice before taking medicine.

Use in pregnancy: It is preferable not to take Trimetazidine Hydrochloride during pregnancy. If pregnancy occurs while taking Trimetazidine Hydrochloride consult the doctor whether to continue the treatment.
Use in lactation: In the absence of data of excretion in the breast milk, breastfeeding is not recommended during treatment.

DOSAGE AND ADMINISTRATION:
Usual Dose: Take one tablet, twice daily (morning and evening)
Tablet should be taken with meals and swallowed with glass of water.
Missed Dose: In case of a missed dose, resume treatment normally. Do not take a double dose to compensate for the single dose that was not taken. If the effect of Trimetazidine Hydrochloride is too strong or too weak, talk to doctor or pharmacist. Should be taken with food. Swallow whole, do not chew/crush.

PREGNANCY AND LACTATION:
There is a limited information on the use of trimetazidine on pregnant women and nursing mothers, As preventive measure it as advised to avoid intake during these events.

OVERDOSE AND TREATMENT:
In case of an overdose, seek emergency medical attention. There is a limited information on trimetazidine overdose. Symptomatic treatment should be done.

ADVERSE EFFECTS:
As with all medicines Trimetazidine Hydrochloride is likely to have side effects, although not everyone may be prone to them.
The following side effects have been reported: Stomach pains, difficulty in digestion, diarrhea, constipation, nausea, vomiting, tiredness; headaches, vertigo, sleep disorders (insomnia, somnolence), aggravation of symptoms similar to Parkinson's disease, which disappear when treatment is stopped; extensive skin rash, itchiness, urticarial sudden swelling of the face and neck due to an allergic reaction, acute generalized exanthematous pustulosis (all over body flushing pustules and accompanied by fever). The onset of these effects can vary from a few hours to several days. Drop in blood pressure upon standing up which may be accompanied by fainting, vertigo or a fall especially in elderly subjects on antihypertensive treatment, palpitations, irregular heartbeats and rapid increase in heartbeats. If some of the side effects become serious, inform the doctor or pharmacist.

REPORTING OF SUSPECTED ADVERSE REACTIONS:
To allow continued monitoring of the benefit/risk balance of the medicinal product, reporting of suspected adverse reaction is necessary. Healthcare professionals are encouraged to report any suspected adverse reactions directly to the importer/distributor and/or report to FDA: www.fda.gov.ph.
Patients are advised to seek immediate medical attention at the first sign/s of adverse reactions.

CAUTION:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

STORAGE CONDITION:
Store at temperature not exceeding 30°C.

AVAILABILITY:
In Alu-Alu Blister Pack of 10's (Box of 30's)

FDA Registration No. : DRP-6781-02
Date of Renewal of Authorization : 08 April 2020
Date of Revision of Package Insert : 28 January 2022

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Manufactured by:
ARISTOPHARMA LTD.
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SAHAR INTERNATIONAL TRADING INC.
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