# **Cardimet®MR**

Trimetazidine Hydrochloride BP Modified Release tablet

## DESCRIPTION

**Cardimet** MR is a preparation of Trimetazidine an anti-anginal drug. By preserving energy metabolism in cells exposed to hypoxia or ischemia, Trimetazidine prevents a decrease in intracellular ATP levels, thereby ensuring the proper functioning of ionic pumps and transmembrane sodium-potassium flow whilst maintaining cellular homeostasis. Trimetazidine inhibits β-oxidation of fatty acids by blocking long-chain 3-ketoacyl-CoA thiolase, which enhances glucose oxidation. In an ischemic cell, energy obtained during glucose oxidation requires less oxygen consumption than in the β-oxidation process. Potentiation of glucose oxidation optimizes cellular energy processes, thereby maintaining proper energy metabolism during ischemia

### INDICATIONS

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 anti-anginal therapies.

#### DOSAGE AND ADMINISTRATION

The dose is one tablet of 35 mg of Trimetazidine twice daily during meals. The benefit of the treatment should be assessed after three months and Trimetazidine should be discontinued if there is no treatment response.

#### CONTRAINDICATIONS

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

#### SIDE FEFFCTS

- · Dizziness, headache
- Abdominal pain, diarrhoea, dyspepsia, nausea and vomiting
- · Rash, pruritus, urticaria
- Asthenia

#### PRECAUTION AND WARNING

This medicine is not a curative treatment for angina attacks, nor is it indicated as an initial treatment for unstable angina or myocardial infarction, nor 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 (medicinal treatment and possibly revascularisation). 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.

#### USE IN PREGNANCY AND LACTATION

There are no data from 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 Trimetazidine during pregnancy. It is unknown whether Trimetazidine is excreted in human milk. A risk to the newborns/infants cannot be excluded. Trimetazidine should not be used during breast-feeding.

#### PHARMACEUTICAL PRECAUTION

Store below  $30^{\circ}\text{C}$  temperature and keep away from light. Do not keep in wet place. Keep out of reach of children.

# **PACKAGING**

Cardimet® MR tablet: Box containing 3 strips of 14 tablets each. Each

modified release tablet contains Trimetazidine
Hydrochloride BP 35 mg.

# SK+F

Manufactured by

# **ESKAYEF PHARMACEUTICALS LTD.**

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