

(As per Innovator's Specification) Trimetazidine Di-hydrochloride (JP Specification)

35mg Modified Released Tablets

#### COMPOSITION

TRIKAT MR 35mg Tablets: Each modified released tablet contains: Trimetazidine Di-hydrochloride ....... 35 mg (As per Innovator's Specification)

#### DESCRIPTION

Trimetazidine Di-hydrochloride is an anti-ischemic (anti-anginal) metabolic agent, which improves myocardial glucose utilization through inhibition of fatty acid metabolism.

## CLINICAL PARTICULARS

#### Therapeutic indications:

TRIKAT MR (Trimetazidine Di-hydrochloride) is intended for use in adult patient, in combination with other medicines to treat angina pectoris (chest pain caused by coronary disease). It protects the heart cells from the effects of a reduced oxygen supply during an episode of angina.

## Dosage and administration:

Oral route. The usual dosage is 1 tablet in the morning and evening. Tablets should be swallowed with a glass of water at meal times.

What to do in case one or several doses have been missed:

Resume treatment normally. A double dose should not be taken to compensate for the single dose that has been missed.

# Contraindications:

Hypersensitivity to the active substance or to any of the excipients. This drug is generally not recommended during breastfeeding.

### Warnings & precautions:

This drug is not a curative treatment for angina attacks, nor an initial treatment for unstable angina pectoris. It is not a treatment for myocardial infarction. In the event of an angina attack, doctor's supervision is needed. Tests and treatment modification may be required.

### Drug interactions:

No drug interactions have been identified.

# Pregnancy:

Studies in animals have not demonstrated a teratogenic effect; however, in the absence of clinical data, the risk of malformation cannot be excluded. Therefore, for safety reasons, prescription should be avoided during pregnancy.

### Lactation:

In the absence of data on excretion in breast milk, breastfeeding is not recommended during treatment.

### Adverse reactions:

As with all drugs, TRIKAT MR (Trimetazidine Di-hydrochloride) is likely to have undesirable effects: rare cases of gastro-intestinal disorders (nausea, vomiting).

### Overdose:

Very limited information is available on Trimetazidine Di-

hydrochloride overdose. Treatment should be symptomatic.

### CLINICAL PHARMACOLOGY

#### Pharmacodynamics:

TRIKAT MR (Trimetazidine Di-hydrochloride) has been proven to exert antianginal properties due to its specific metabolic mechanism of action. TRIKAT MR (Trimetazidine Dihydrochloride) reduces the metabolic damage caused during ischemia, by acting on a critical step (fatty acid b-oxidation) in cardiac metabolism. This is made possible by a selective inhibition of an enzyme of fatty acid b-oxidation: the long-chain 3-ketoacyl CoA thiolase (3-KAT). This inhibition results in reduction in fatty acid oxidation and stimulation of glucose oxidation. Thus, the coupling of glycolysis with glucose oxidation is improved and ATP production is further increased, while cell acidosis and Ca+2 overload are limited.

#### Pharmacokinetics:

It is well absorbed and metabolized in the liver to inactive metabolites, then excreted in urine with a  $t \frac{1}{2}$  of 5-6 hours.

#### STORAGE

Store below 30°C. Protect from light and moisture.

# **HOW SUPPLIED**

TRIKAT MR 35mg Tablet: Pack of 20 modified released tablets.

TO BE SOLD ON THE PRESCRIPTION OF A REGISTERED MEDICAL PRACTITIONER ONLY

KEEP ALL MEDICINES OUT OF THE REACH OF CHILDREN.

Contains Lactose But Gluten Free

ٹرائی کیٹ ایم آر (ٹرائی میٹازیڈین ڈائی ہائیڈروکلورائیڈ) 35 ملى گرام موڈ بفائیڈر بلنز ڈ گولیاں

ڈاکٹر کی مدایات کےمطابق استعمال کریں۔ صرف متنددٌ اکثر کے نسخہ کے مطابق ہی دوا فروخت کی جائے۔ تمام ادویات بچوں کی پینچ سے دورر تھیں۔ دواکو ℃30 سے کم درجہ ترارت پر بنجی اور روثنی سے محفوظ ر تھیں۔