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TRIMETAZIDINE HYDROCHLORIDE

CARVIDON MR™

35 mg Modified-Release Tablet
ANTI-ANGINA

PRODUCT NAME
Trimetazidine Tablets

NAME AND STRENGTH:
Trimetazidine Tablets 35 mg

PHARMACOLOGIC CATEGORY:
ANTI-ANGINA

PRODUCT DESCRIPTION
Light Pink colored, circular biconvex, film coated tablets

FORMULATION/COMPOSITION:
Each film-coated modified release tablet contains:
Trimetazidine Hydrochloride BP ..... 35 mg

PHARMACODYNAMICS/PHARMACOKINETICS:
Pharmacodynamics:
Mechanism of action
Trimetazidine inhibits β-oxidation of fatty acids by blocking long-chain 3-ketoacyl-CoA thiolase (3-KAT), which enhances glucose oxidation. In an ischaemic 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 ischaemia.
Pharmacodynamic effects.
In patients with ischemic heart disease, Trimetazidine acts as a metabolic agent, preserving the myocardial high-energy phosphate intracellular levels. Ant ischemia effects are achieved without concomitant hemodynamic effects.

Pharmacokinetics:
Orally, the maximum concentration is on average five hours after taking the tablet. About 24 hours, the plasma concentration is maintained at concentrations greater than or not equal to 75% of the maximum concentration for 11 hours.
The steady state is reached, no later than the 60th hour.
The pharmacokinetic characteristics of Trimetazidine are not influenced by meal.
The apparent volume of distribution is 4.8 L/kg, the determination of Trimetazidine protein is weak: the value measured in vitro is 16%.
The elimination of Trimetazidine is mainly via the kidneys, mainly in the form of the unchanged product.
The half-life of Trimetazidine is an average of 7 hours in healthy young volunteers, and 12 hours in the elderly over 65 years.
The total clearance of Trimetazidine is the one that results from renal clearance majority directly related to creatinine clearance and to a lesser value, a hepatic clearance that decreases with age.
A specific clinical study, conducted in an elderly population, with a dose of 2 tablets per day in two doses, as measured by population kinetic data showed an increase in plasma exposure did not justify any change in dosage.

INDICATIONS:
It is intended for use in the management of angina pectoris. It has been shown in a few studies to be useful in the management of certain disorders of ischemic origin affecting the cochleovestibular structures or the chorioretinal tissue.

DOSAGE AND MODEL ROUTE OF ADMINISTRATION:
Oral administration. One tablet in the morning and evening. It should be taken along with food.

CONTRAINDICATIONS &PRECAUTION(S), WARNING(S):
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

PRECAUTIONS & WARNINGS:
This drug is not a curative treatment for angina attacks, nor is indicated as an initial treatment for unstable angina pectoris or myocardial infarction. It should not be used in the prehospital phase nor during the first days of hospitalisation.
In the event of an angina attack, angina pectoris disease should be revaluated and an adaptation of the treatment considered.
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 withdrawal. If Parkinsonian symptoms persist more than 4 months after drug discontinuation, a neurologist's 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 patients in whom an increased exposure is expected: moderate renal impairment; elderly patients older than 75 years old

Size: 170 x 240 mm

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PREGNANCY AND LACTATION:
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.

INTERACTIONS:
No drug interactions have been identified.

ADVERSE EFFECTS:

System Organ Class	Frequency	Preferred Term
Nervous system disorders	Common	Dizziness, headache
	Not known	Parkinsonian symptoms (tremor, akinesia, hypertonia), gait instability, restless leg syndrome, other related movement disorders, usually reversible after treatment discontinuation
	Not known	Sleep disorders (insomnia, drowsiness)
Cardiac disorders	Rare	Palpitations, extra systoles, tachycardia
Vascular disorders	Rare	Arterial Hypotension , Orthostatic hypotension that may be associated with malaise, dizziness or fall, in particular in patients taking antihypertensive treatment, flushing
Gastrointestinal disorders	Common	Abdominal pain, diarrhoea, dyspepsia, nausea and vomiting
	Not known	Constipation
Skin and subcutaneous tissue disorders	Common	Rash, pruritus, urticaria.
	Not known	Acute generalized exanthematous pustulosis (AGEP), angioedema
General disorders and administration conditions	Common	Asthenia
Blood and lymphatic system disorders	Not known	Agranulocytosis Thrombocytopenia Thrombocytopenic purpura
Hepatobiliary disorders	Not known	Hepatitis

OVERDOSAGE AND TREATMENT:
Very limited information is available on Trimetazidine overdose. Treatment should be symptomatic.

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

DOSAGE FORMS AND PACKAGING AVAILABLE:
Trimetazidine (Carvidon MR) Tablets 35 mg are packed in Alu/PVC blister pack of 10's (Box of 100's)

INSTRUCTIONS AND SPECIAL PRECAUTIONS FOR HANDLING AND DISPOSAL (IF APPLICABLE):
Not Applicable

NAME AND ADDRESS OF MARKETING AUTHORIZATION HOLDER:
Marketing Authorization Holder
Brown & Burk Philippines Inc.
U-501, 5/F., SEDCCO 1 Bldg., 120 Rada cor.
Legaspi Sts., Legaspi Village, Makati City, Philippines

NAME AND ADDRESS OF MANUFACTURER:
MICRO LABS LIMITED Unit III
R.S. No. 63/3&4, Thiruvandar Koil,
Pondicherry-605 102. India.

CAUTION STATEMENT:
FOODS, DRUGS, DEVICES, AND COSMETICS ACT PROHIBITS DISPENSING WITHOUT PRESCRIPTION.

ADR REPORTING STATEMENT:
"FOR SUSPECTED ADVERSE DRUG REACTION, REPORT TO THE FDA: www.fda.gov.ph
Seek medical attention immediately at the first sign of Adverse Drug Reaction.

REGISTRATION NUMBER:
DRP - 983

DATE OF FIRST AUTHORIZATION:
21ST July 2015

DATE OF REVISION OF PACKAGE INSERT:
Feb. 2017

EXG-ML05I-0014/E

Size: 170 x 240 mm

MICRO LABS LIMITED, BANGALORE, INDIA			
1	Product Name	Carvidon MR	Colours Used
2	Strength	35 mg	
3	Component	Leaflet	BLACK
4	Category	Export - Philippines	
5	Dimension	170 x 240 mm	
6	Artwork Code	EXG-ML05I-0014/E	
7	Pharma Code	N/A	
8	Reason for Change	Distributed by deleted	

	Prepared by (DTP)	Checked by (PD)	Approved by			
			Head CQA	Head Production/ Packing (Site)	Head QC (Site)	Head QA (Site)
Sign	Kantharaju L.					
Date	19-12-2019					