MICRO LABS LIMITED, BANGALORE, INDIA			
1	Product Name	Calcivas	Colours Used
2	Strength	5 mg & 10 mg	■ BLACK
3	Component	Leaflet	
4	Category	Export - Philippines	
5	Dimension	120 x 170 mm	
6	Artwork Code	EXG-ML01I-1679	
7	Pharma Code	N/A	
8	Reason for Change	New Regulation	

	Prepared by (DTP)	Checked by (PD)	Approved by			
			Head CQA	Head Production/ Packing (Site)	Head QC (Site)	Head QA (Site)
Sign	Kantharaju L.					
Date	27-08-2020					

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AMLODIPINE BESILATE

CALCIVAS™

5 mg Tablet
10 mg Tablet
ANTIHYPERTENSIVE

PRODUCT NAME:
CALCIVAS

DOSAGE FORM AND STRENGTH:
Amlodipine Besilate 5/10mg

PHARMACOLOGIC CATEGORY: Anti hypertensive

PRODUCT DESCRIPTION
White to off white, flat, circular, bevel edged, uncoated tablets with a breakline on one surface and plain on other side

FORMULATION/COMPOSITION:
Each uncoated tablet contains:
Amlodipine (as Besilate)..... 5 mg
Amlodipine (as Besilate)..... 10 mg

Pharmacodynamics
Amlodipine is a dihydropyridine calcium antagonist that inhibits the transmembrane influx of calcium ions into the smooth muscle and cardiac muscle. The mechanism of the antihypertensive action is due to a direct relaxant effect on vascular smooth muscle. The precise
Mechanism by which Amlodipine relieves angina may be due to the following two actions:

- Amlodipine dilate & peripheral arterioles and thus reduces the total peripheral resistance against which the heart works. Since there is no associated for the electiveness of Amlodipine in myocardial ischemia.
- The mechanism of action of Amlodipine probably involves dilation of the main coronary arterial and coronary arterioles, both in normal and ischaemic regions.

Pharmacokinetics:
Amlodipine is well absorbed following oral administration with peak blood concentration occurring after 6 to 12 hours. The bioavailability is about 60 to 65%. It is reported to be about 97.5% bound to plasma proteins. It has a prolonged terminal elimination half life of 35 to 50 hours and steady-state plasma concentration is & not achieved until 7 to 8 days of administration. Amlodipine is extensively metabolised in the liver, metabolites are mostly excreted in urine together with less then 10% of a dC48 as unchanged drug.

INDICATIONS:
Amlodipine is a dihydropyridine calcium channel blocker and it is used in the management of hypertension and prophylaxis of angina pectoris

DOSAGE AND MODEL ROUTE OF ADMINISTRATION:
In hypertension the usual initial dose is 5 mg once daily, increased, if necessary, to 10 mg once daily. Similar doses are given in the treatment of stable angina and Prinzmetal's angina. Or as prescribed by the physician

CONTRAINDICATIONS &PRECAUTION(S), WARNING(S)
Amlodipine is contraindicated in patients with known hypersensitive to Amlodipine

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PRECAUTIONS AND WARNINGS:
Should be used with caution in patients with hypotension, in patients whose cardiac reserve is poor, and in those with heart failure since deterioration of heart failure has been noted. It should not be used in cardiogenic shock, in patients who have recently suffered myocardial infraction or in acute unstable angina.

DRUG INTERACTIONS:
Amlodipine has been safely administered with thiazide diuretics, beta-adrenoreceptor blocking drugs, angiotensin converting enzyme inhibitor, long acting nitrates & sublingual glyceryl nitrate, non steroidal anti-inflammatory drugs, antibiotics and oral hypoglycaemic agents. Co-administration of Cimetidine did not alter the pharmacokinetics of Amlodipine. In vitro data from studies with human plasma indicate that Amlodipine has no effect on protein binding of Digoxin, Phenytoin, Warfarin or Indomethacin.

ADVERSE EFFECTS:
The most commonly observed adverse effects were dizziness, flushing, headache, hypotension, peripheral oedema, tachycardia, and palpitation. Nausea and other gastrointestinal disturbances, increased micturition frequency, lethargy, eye pain and mental depression have also occurred. A paradoxical increase in ischemic chest pain may occur at the start of treatment and in few patients excessive fall in blood pressure has led to cerebral or myocardial ischemia or transient blindness.

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

DOSAGE FORMS AND PACKAGING AVAILABLE:
Amlodipine Besilate 5 mg Tablet Alu/Alu Blister pack of 10's (Box of 50's)
Amlodipine Besilate 10 mg Tablet Alu/Alu Blister pack of 10's (Box of 30'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
92, SIPCOT, HOSUR – 635 126.
TAMIL NADU, 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 sigh of Adverse Drug Reaction.

REGISTRATION NUMBER:
Calcivas 5 mg : DRP-816
Calcivas 10 mg : DRP-832

DATE OF FIRST AUTHORIZATION:
-

DATE OF REVISION OF PACKAGE INSERT:
Sep. 2019

EXG-ML01I-1679

Size: 120 x 170 mm