MICRO LABS LIMITED, BANGALORE, INDIA			
1	Product Name	Turbovas-20	Colours Used
2	Strength	20 mg	
3	Component	Leaflet	■ BLACK
4	Category	Export - Philippines	
5	Dimension	120 x 170 mm	
6	Artwork Code	EXG-ML01I-1152/A	
7	Pharma Code	N/A	
8	Reason for Change	New text	

	Prepared by (DTP)	Checked by (PD)	Approved by			
			Head CQA	Head Production/ Packing (Site)	Head QC (Site)	Head QA (Site)
Sign	Kantharaju L.					
Date	24-05-2021					

⬇ Front

ROSUVASTATIN CALCIUM

TURBOVAS-20

20 mg Film-Coated Tablet
HMG CoA Reductase Inhibitor

PRODUCT NAME: Turbovas-20

DOSAGE FORM AND STRENGTH: Rosuvastatin Calcium 20mg

PHARMACOLOGIC CATEGORY: HMG CoA Reductase Inhibitor

PRODUCT DESCRIPTION:
Orange coloured, circular, biconvex film-coated tablets with 'MICRO' engraved on one surface and plain on other surface.

FORMULATION/COMPOSITION:
Each film-coaled tablet contains:
Rosuvastatin Calcium equivalent to Rosuvastatin ..... 20 mg

Pharmacokinetics:
Rosuvastatin is incompletely absorbed from the gastrointestinal tract, with an absolute bioavailability of about 20%. Peak plasma concentrations are achieved about 5 hours after an oral dose. It is taken up extensively by the liver, Its primary site of action, and undergoes limited metabolism, mainly by the cytochrome P450 isoenzyme CYP2C9. Il is about 90% bound to plasma proteins. The plasma elimination half-life of rosuvastatin is about 19 hours. About 90% of an oral dose of rosuvastatin appears in the faeces, including absorbed and non-absorbed drug, and the remainder is excreted in the urine; about5% of a dose is excreted unchanged in urine.

INDICATIONS:
Used to reduce LDL cholesterol, apolipoprotein B, and triglycerides, and to Increase HDL-cholesterol in the management of Hyperlipidemias including primary Hypercholesterolemia (type IIa), mixed dyslipidaemia (type IIb), and hypertriglyceridemia (type IV), as well as in patients with homozygous familial Hypercholesterolemia. It is also used to reduce the progression of atherosclerosis.

DOSAGE AND MODEL ROUTE OF ADMINISTRATION:
The usual initial dose of rosuvastatin is 5 or 10 mg once daily, depending on plasma-cholesterol concentrations, cardiovascular risk factors, and risk factors for adverse effects. The maintenance dose ranges from 5 to 40 mg once daily, although the 40-mg dose is reserved for patients with high cardiovascular risk who do not achieve their target cholesterol concentration at lower doses and who do not have risk factors for adverse effects. For patients with severe renal Impairment (CLcr <30 mL/min/1. 73 m) not on haemodialysis, dosing of Rosuvastatin should be started at 5 mg once daily and not exceed 10mgoncedaily.

CONTRAINDICATIONS &PRECAUTION(S), WARNING(S)
Rosuvastatin is contraindicated in patients with a known hypersensitivity to any component of this product. Rosuvastatin is contraindicated in patients with active liver disease or with unexplained persistent elevations of serum transaminases

PRECAUTIONS AND WARNINGS:
Rosuvastatin should be used with caution in patients with renal impairment as the risk of myopathy is increased. Dose reduction may be required for rosuvastatin that are excreted by the kidney and for those with a particularly high risk of myopathy.
Liver Enzymes HMG-CoA reductase inhibitors, like some other lipid-lowering therapies, have been associated with biochemical abnormalities of liver function. The Incidence of persistent elevations (>3 times the upper limit of normal

⬇ Back

[ULN] occurring on 2 or more consecutive occasions) in serum transaminases in fixed dose studies was DA, 0, 0, and 0.1 % in patients who received rosuvastatin 5, 10, 20, and 40 mg, respectively. In most cases, the elevations were transient and resolved or improved on continued therapy or after a brief Interruption In therapy. There were two cases of jaundice, for which a relationship to rosuvastatin therapy could not be determined, which resolved after discontinuation of therapy. There were no cases of liver failure or irreversible liver disease in these trials. Il is recommended that liver function tests be performed before and al 12 weeks following both the initiation of therapy and any elevation of dose, and periodically (e.g .. semi-annually) thereafter. Liver enzyme changes generally occur in the first 3 months of treatment with rosuvastatin. Patients who develop increased transaminase levels should be monitored until the abnormalities have resolved. Should an Increase In ALT or AST of >3 times ULN persist, reduction of dose or withdrawal of rosuvastatin Is recommended.

INTERACTIONS:
Rosuvastatin undergoes limited metabolism, principally by the cytochromeP450 isoenzyme CYP2C9, and may not have the same Interactions with enzyme Inhibitors as simvastatin. However, increased plasma-rosuvastatin concentrations have been reported with ciclosporin, HIV protease inhibitors, and, to a lesser extent with gemfibrozil, and such combinations should be avoided. If they must be given together, lower doses of rosuvastatin should be used. Rosuvastatin is contraindicated with ciclosporin.

ADVERSE EFFECTS:
The commonest adverse effects of therapy with rosuvastatin are gastrointestinal disturbances. Other adverse affects reported include headache, skin rashes, dizziness, blurred vision, insomnia, and dysgeusia. Reversible increases in serum-aminotransferase concentrations may occur and liver function should be monitored. Hepatitis and pancreatitis have been reported. Hypersensitivity reactions including anaphy1axis and angioedema have also occurred. Myopathy characterized by myalgia and muscle weakness and associated with Increased creatine phosphokinase concentrations has bean reported, especially in patients also taking ciclosporin, fibric acid derivatives, or nicotinic acid. Rarely, rhabdomyolysis with acute renal failure may develop.

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

DOSAGE FORMS AND PACKAGING AVAILABLE:
Rosuvastatin 20 mg FCT (Turbovas-20): Alu/Alu Blister pack 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:
DR-XY43884

DATE OF FIRST AUTHORIZATION:
12 November 2014

DATE OF REVISION OF PACKAGE INSERT:
Sep. 2019

EXG-ML01I-1152/A

Size: 120 x 170 mm
Folding size: 30 x 120 mm
Carton size: 53 x 25 x 130 mm