MICRO LABS LIMITED, BANGALORE, INDIA			
1	Product Name	Melanov MR 60	Colours Used
2	Strength	60 mg	■ BLACK
3	Component	Leaflet	
4	Category	Export - Philippines	
5	Dimension	120 x 170 mm	
6	Artwork Code	EXG-ML05I-0198/B	
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	18-01-2020					

Front

Back

GLICLAZIDE

MELANOV MR 60

60 mg Modified Release Tablet
ORAL HYPOGLYCEMIC

PRODUCT NAME: MELANOV MR 60

NAME AND STRENGTH: Gliclazide Modified-Release Tablets 60 mg

PHARMACOLOGIC CATEGORY: ORAL HYPOGLYCEMIC

PRODUCT DESCRIPTION:
White, Caplet shaped uncoated tablets with breakline on one surface and plain on the other

FORMULATION/COMPOSITION:
Each uncoated modified release tablet contains:
Gliclazide..... 60 mg

PHARMACOKINETICS:
Gliclazide is readily absorbed from the gastrointestinal tract. It is extensively bound to plasma proteins. The half-life is about 10 to 12 hours. It is extensively metabolized in the liver to metabolites that have no significant hypoglycemic activity. Metabolites and a small amount of unchanged drug are excreted in the urine.

INDICATIONS:
For the treatment of type 2 diabetes mellitus

DOSAGE AND MODEL ROUTE OF ADMINISTRATION:
The daily dose may vary from ½-2 tab daily (30-120 mg) taken orally in a single intake at breakfast. As with any hypoglycaemic agent, the dose should be adjusted according to the individual patient's metabolic response (blood glucose, HbAIc).

CONTRAINDICATIONS &PRECAUTION(S), WARNING(S)
Contraindicated in patients with ketoacidosis and in those with severe infection, trauma, or other severe conditions where the sulfonylurea is unlikely to control the hypoglycemia.

PRECAUTIONS & WARNINGS
Caution is needed in the elderly and in those with mild to moderate hepatic and renal impairment because of the hazard of hypoglycemia. The short acting tolbutamide may be used in renal impairment, as may gliclazide which is primarily metabolized in the liver. Careful monitoring of blood glucose concentration is essential among these patients with renal or hepatic dysfunction; care is required to choose the smallest possible dose that produce adequate control of blood glucose.

INTERACTIONS:
Rifampicin and thiazide diuretics are the compounds that may diminish the hypoglycemic effects and there necessitate an increase in the dosage requirement of gliclazide. There is also a theoretical risk of diminished hypoglycemic effect with adrenalin, aminoglutethimide, chlorpromazine, corticosteroids, diazoxide, oral contraceptives, rifamycins, and thiazide diuretics.
Alcohol may have a variable effect of its own on blood-glucose concentrations; there is a general tendency to increase hypoglycemic effect when alcohol and gliclazide are taken concurrently.

ADVERSE EFFECTS:
Gastrointestinal disturbances such as nausea, vomiting, heartburn, anorexia, diarrhoea, and metallic taste may occur with sulfonylureas and are usually mild and dose-dependent; increased appetite and weight gain may also occur. Skin rashes and pruritus may occur and photosensitivity has been reported.

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

DOSAGE FORMS AND PACKAGING AVAILABLE:
Gliclazide (Melanov MR 60) 60 mg modified release tablet Alu/PVC Blister pack x10's (box of 30's)
Gliclazide (Melanov MR 60) 60 mg modified release tablet Alu/PVC Blister pack x10'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, 63/3&4, Thiruvandar Koil.
Puducherry – 605102, 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:
DRP-7997

DATE OF FIRST AUTHORIZATION:
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DATE OF REVISION OF PACKAGE INSERT: June 2019

EXG-ML05I-0198/B

Size: 120 x 170 mm