Size: 120 (L) x 240 (H) mm
Folding size: 30 x 120 mm
Carton size: 46 x 46 x 102 mm

Front

METFORMIN Hydrochloride

MELMET-850

850 mg Film-Coated Tablet

ORAL HYPOGLYCEMIC AGENT (BIGUANIDE)

PRODUCT NAME:
MELMET-850

NAME AND STRENGTH:
Metformin Hydrochloride 850 mg

PHARMACOLOGIC CATEGORY:
ORAL HYPOGLYCEMIC AGENT (BIGUANIDE)

PRODUCT DESCRIPTION:
White, Circular, biconvex, film-coated tablets plain on both surfaces.

FORMULATION/COMPOSITION:
Each film-coated tablet contains:
Metformin Hydrochloride ..... 850 mg

PHARMACODYNAMICS/PHARMACOKINETICS:
Metformin Hydrochloride is slowly and incompletely absorbed from gastrointestinal tract; the absolute bioavailability of a single 500 mg dose is reported to be about 50 to 60%, although this is reduced some what if taken with food. Following absorption plasma protein binding is negligible, and it is excreted unchanged in the urine. The plasma elimination half life is reported to range from about 2 to 6 hours after oral administration.

INDICATIONS:
Metformin hydrochloride is a biguanide antidiabetic. It is indicated to treat type 2 diabetes mellitus and is the drug of first choice in obese patients.

DOSAGE AND MODEL ROUTE OF ADMINISTRATION:
Initial dosage is 500 mg two or three times daily or 850 mg once or twice daily with or after meal, gradually increased if necessary to 2 to 3 g daily; doses above 2 g daily are associated with an increased incidence of gastrointestinal adverse effects or as prescribed by the physician.

CONTRAINDICATIONS &PRECAUTION(S), WARNING(S):
Hypersensitivity to metformin hydrochloride

PRECAUTIONS & WARNINGS:
Metformin Hydrochloride is in a appropriate for patients with diabetic coma and ketoacidosis, or for those with severe infection, trauma, or other severe condition where the biguanide is unlikely to control hyperglycaemia; insulin should be administered in such situation. Metformin should not be given to patients with mild impairment of renal function, heart failure recent myocardial infarction, dehydration, hepatic impairment or any other condition likely to predispose to lactic acidosis.

PREGNANCY AND LACTATION:
Pregnancy
A limited amount of data from the use of metformin in pregnant women does not indicate an increased risk of congenital abnormalities. Animal studies do not indicate harmful effects with respect to pregnancy, embryonic or foetal development, parturition or postnatal development.
When the patient plans to become pregnant and during pregnancy, it is recommended that diabetes is not treated with metformin but insulin be used to maintain blood glucose levels as close to normal as possible, to reduce the risk of malformations of the foetus.
Lactation
Metformin is excreted into human breast milk. No adverse effects were observed in breastfed newborns/infants. However, as only limited data are available, breast-feeding is not recommended during metformin treatment. A decision on whether to discontinue breast-feeding should be made, taking into account the benefit of breast-feeding and the potential risk to adverse effects on the child.

INTERACTIONS:
Concomitant use not recommended
Alcohol
Alcohol intoxication is associated with an increased risk of lactic acidosis, particularly in case of fasting, malnutrition or hepatic impairment.
Iodinated contrast agents
Metformin must be discontinued prior to or at the time of the imaging procedure and not restarted until at least 48 hours after, provided that renal function has been re-evaluated and found to be stable

Back

Combinations requiring precautions for use
Some medicinal products can adversely affect renal function which may increase the risk of lactic acidosis, e.g. NSAIDs, including selective cyclo-oxygenase (COX) II inhibitors, ACE inhibitors, angiotensin II receptor antagonists and diuretics, especially loop diuretics. When starting or using such products in combination with metformin, close monitoring of renal function is necessary.
Medicinal products with intrinsic hyperglycemic activity (e.g. glucocorticoids (systemic and local routes) and sympathomimetics)
More frequent blood glucose monitoring may be required, especially at the beginning of treatment. If necessary, adjust the metformin dosage during therapy with the respective medicinal product and upon its discontinuation.
Organic cation transporters (OCT)
Metformin is a substrate of both transporters OCT1 and OCT2.
Co-administration of metformin with

- Inhibitors of oct1 (such as verapamil) may reduce efficacy of metformin.
- Inducers of oct1 (such as rifampicin) may increase gastrointestinal absorption and efficacy of metformin.
- Inhibitors of oct2 (such as cimetidine, dolutegravir, ranolazine, trimethoprim, vandetanib, isavuconazole) may decrease the renal elimination of metformin and thus lead to an increase in metformin plasma concentration.
- Inhibitors of both OCT1 and OCT2 (such as crizotinib, olaparib) may alter efficacy and renal elimination of metformin.

Caution is therefore advised, especially in patients with renal impairment, when these drugs are co-administered with metformin, as metformin plasma concentration may increase. If needed, dose adjustment of metformin may be considered as OCT inhibitors/inducers may alter the efficacy of metformin.

ADVERSE EFFECTS:
Gastrointestinal disturbances including anorexia, nausea and diarrhoea

OVERDOSAGE AND TREATMENT:
Hypoglycaemia has not been seen with metformin hydrochloride doses of up to 85g, although lactic acidosis has occurred in such circumstances. High overdose of metformin or concomitant risks may lead to lactic acidosis. Lactic acidosis is a medical emergency and must be treated in hospital. The most effective method to remove lactate and metformin is haemodialysis.

STORAGE CONDITION:
STORE AT TEMPERATURES NOT EXCEEDING 30°C.

DOSAGE FORMS AND PACKAGING AVAILABLE:
Film-Coated Tablets Blister Pack of 10's (Box of 50'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 Metro Manila

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 sign of Adverse Drug Reaction.

REGISTRATION NUMBER:
DR NO: DRP-1869

DATE OF FIRST AUTHORIZATION:
09 JULY. 2009

DATE OF REVISION OF PACKAGE INSERT:
Mar. 2021

EXG-ML01I-1151/A

240 mm

120 mm

120 mm

MICRO LABS LIMITED, BANGALORE, INDIA			
1	Product Name	Melmet-850	Colours Used
2	Strength	850 mg	BLACK
3	Component	Leaflet	
4	Category	Export - Philippines	
5	Dimension	120 x 240 mm	
6	Artwork Code	EXG-ML01I-1151/A	
7	Pharma Code	N/A	
8	Reason for Change	Size and 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	19-11-2021					