MICRO LABS LIMITED, BANGALORE, INDIA			
1	Product Name	Etorica-60/90/120	Colours Used
2	Strength	60 mg, 90 mg and 120 mg	BLACK
3	Component	Leaflet	
4	Category	Export - Philippines	
5	Dimension	120 (L) x 240 (H) mm	
6	Artwork Code	EXG-ML05I-0323	
7	Pharma Code	N/A	
8	Reason for Change	New Artwork	

	Prepared by (DTP)	Checked by (PD)	Approved by			
			Head CQA	Head Production/ Packing (Site)	Head QC (Site)	Head QA (Site)
Sign	Kantharaju L.					
Date	12-01-2023					

Size: 120 (L) x 240 (H) mm
Folding size: 30 x 120 mm
Carton size: 53 x 25 x 130 mm

Front

Back

240 mm

120 mm

120 mm

ETORICOXIB

ETORICA

60 mg/90 mg/120 mg Film Coated Tablet
Selective Cox-2 Inhibitor

PRODUCT NAME:
ETORICA

DOSAGE FORM AND STRENGTH:
Film-coated tablet 60/90/120 mg

PHARMACOLOGIC CATEGORY:
Selective Cox-2 Inhibitor

PRODUCT DESCRIPTION:
Etorica 60 mg: Light greenish yellow coloured, circular, biconvex, film-coated tablets with breakline on one surface and plain on other surface.
Breakline is to facilitate breaking for ease of swallowing and not for dividing into equal doses.
Etorica 90 mg: Green coloured, circular, biconvex, film-coated tablets plain on both surfaces.
Etorica 120 mg: Yellow coloured, circular, biconvex, film-coated tablets plain on both surfaces.

FORMULATION/COMPOSITION:
Each film-coated tablet contains:
Etoricoxib ……..……60 mg
Etoricoxib ……..…… 90 mg
Etoricoxib ……..…… 120 mg

PHARMACOKINETICS:
Etoricoxib is well absorbed from the gastrointestinal tract after oral doses. Peak plasma concentrations are reached in approximately 1 hour and plasma protein binding is about 92%. At steady state the half-life of etoricoxib is about 22 hours. Etoricoxib is extensively metabolised with less than 2% of a dose recovered in the urine as the parent drug. The major route of metabolism is via cytochrome P450 isoenzymes including CYP3A4 to form the 6"hydroxymethyl derivative of etoricoxib, which is then oxidized to the 6"-carboxylic acid derivative, the major metabolite. Both are inactive or only weak cycle>-oxygenase-2 (COX-2) inhibitors. Excretion is mainly via the urine (70%) with only 20% of a dose appearing in the faeces.

INDICATIONS:
It is used in the symptomatic relief of rheumatoid arthritis, osteoarthritis, and acute gouty arthritis.

DOSAGE AND MODE ROUTE OF ADMINISTRATION:
In osteoarthritis, etoricoxib is given by mouth in a usual dose of 30 mg once daily, increased if necessary to 60 mg once daily. The recommended dose in rheumatoid arthritis is 90 mg once daily; higher doses of 120 mg once daily are used in gouty arthritis although such doses should only be used for the acute symptomatic period and for a maximum of 8 days. Or as prescribed by the physician

WARNING:
Absolute contraindications:
Not to be given to those patients who have history of:
- Stroke : cerebrovascular accident, CVA
- Heart Attack: Myocardial infarction, MI
- Coronary artery bypass graft; CABG
- Uncontrolled hypertension
- Congestive heart failure (CHF) NYHAII-IV

COX-2 Inhibitors are not to be given to patients with allergy to NSAID's and those with asthma. Exercise caution when prescribing Selective COX-2 inhibitors in patients with ischaemic heart disease and those with risk factors for heart disease; hypertension; hyperlipidemia, diabetes, smoking and patients with peripheral arterial disease. Considering association between cardiovascular risk and exposure to COX-2 inhibitors, doctors are advised to use the lowest effective dose for the shortest duration of treatment. Intake of COX-2 inhibitors should be stopped with appearance of skin rash and signs of hypersensitivity.

CONTRAINDICATIONS :
Etoricoxib is also contraindicated in patients with inflammatory bowel disease, moderate to severe heart failure, and renal impairment associated with a creatinine clearance of less than 30 mL/minute.

PRECAUTIONS AND WARNINGS:
Etoricoxib should not be used in patients with a history of ischaemic heart disease or cerebrovascular disease. It should be used with caution in patients with significant risk factors for cardiovascular disease or peripheral arterial disease. Etoricoxib, particularly at high doses, may be associated with more frequent and severe hypertension compared with other NSAIDs and selective COX-2 inhibitors; blood pressure monitoring during etoricoxib treatment is recommended. It should not be used in patients with hypertension whose blood pressure is not controlled

PREGNANCY AND LACTATION:
Pregnancy
No clinical data on exposed pregnancies are available for Etoricoxib. Studies in animals have shown reproductive toxicity. The potential for human risk in pregnancy is unknown. Etoricoxib, as with other medicinal products inhibiting prostaglandin synthesis, may cause uterine inertia and premature closure of the ductus arteriosus during the last trimester. Etoricoxib is contraindicated in pregnancy. If a woman becomes pregnant during treatment, Etoricoxib must be discontinued.
Lactation
It is not known whether Etoricoxib is excreted in human milk. Etoricoxib is excreted in the milk of lactating rats. Women who use Etoricoxib must not breast feed.
Fertility
The use of Etoricoxib, as with any drug substance known to inhibit COX-2, is not recommended in women attempting to conceive.

INTERACTIONS:
The metabolism of etoricoxib is mediated by the cytochrome P450 isoenzyme CYP3A4. Use with other drugs that inhibit or induce this isoenzyme may result in changes in plasma concentration of Etoricoxib. In addition, in vitro studies suggest that several other isoenzymes may also mediate the main metabolic pathway of Etoricoxib. Rifampicin, a potent inducer of CYP isoenzymes, has produced decreased plasma concentrations of etoricoxib.
Etoricoxib is an inhibitor of human sulfotransferases activity and has been shown to increase the plasma concentration of ethinylestradiol. Interactions with other drugs, such as oral salbutamol and minoxidil, also metabolised by this enzyme may be a possibility and licensed product information advises care with such combinations.

STORAGE CONDITION:
Store at temperatures not exceeding 30°C

DOSAGE FORMS AND PACKAGING AVAILABLE:
Etoricoxib 60 mg Film Coated Tablet Packed in Alu-Alu blister pack by 10's (Box of 30's)
Etoricoxib 90 mg Film Coated Tablet Packed in Alu-Alu blister pack by 10's (Box of 30's)
Etoricoxib 120 mg Film Coated Tablet Packed in Alu-Alu blister pack by 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
UNIT-III, R.S. No. 63/3 & 4,
Thiruvandar Koil, Mannadipet Commune,
Puducherry-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 sigh of Adverse Drug Reaction.

REGISTRATION NUMBER:
Etoricoxib Tablets 60 mg: DRP-12815
Etoricoxib Tablets 90 mg: DRP-12816
Etoricoxib Tablets 120 mg: DRP-12814

DATE OF FIRST AUTHORIZATION:
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DATE OF REVISION OF PACKAGE INSERT:
January 2023

EXG-ML05I-0323