ETORICOXIB

Rx

XIBRA-90

90 mg Film-Coated Tablet
Selective COX-2 Inhibitor

FORMULATION:
Each film-coated tablet contains:
Etoricoxib.....90 mg

PRODUCT DESCRIPTION:
A light blue- colored, oval and biconvex film coated tablet having no identification mark.

PHARMACOKINETICS:
Etoricoxib is well absorbed from the gastrointestinal tract after oral doses. Peak plasma concentrations are reached in about 1 hour in fasted adults; food delays absorption by about 2 hours, although it has no effect on the extent of absorption. Plasma protein binding is about 92%. At steady state the half-life of etoricoxib is about 22 hours. Etoricoxib is extensively metabolized 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 cyclo-oxygenase-2 (COX-2) inhibitors. Excretion is mainly via the urine (70%) with only 20% of a dose appearing in the faeces. Studies in animals suggest that etoricoxib may cross the placenta and that some is distributed into breast milk.

INDICATIONS:
Etoricoxib is Non-Steroidal Anti-Inflammatory Drug (NSAID) reported to be a Selective Inhibitor of Cyclo-Oxygenase-2 (COX-2). It is used in the symptomatic relief of Rheumatoid Arthritis, Osteoarthritis, and Acute Gouty Arthritis.

DRUG 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 sulfotransferase activity and has been shown to increase the plasma concentration of ethinylestradiol. Interactions with other drugs, such as oral salbutamol and minoxidil, also metabolized by this enzyme may be possibility and licensed product information advises care with such combinations.

CONTRAINDICATIONS:
Etoricoxib is also contraindicated in patients with inflammatory bowel disease, moderate to severe heart failure (NYHA class II to IV), and renal impairment associated with a creatinine clearance of less than 30 mL/ minute. Caution is recommended when using Etoricoxib in dehydrated patients, it may be advisable to rehydrate patients before giving etoricoxib.

ABSOLUTE CONTRAINDICATIONS:
Not to be given to those patients who have history of:

- Stroke: Cerebrovascular Accident, CVA
- Heart Attack: Myocardial Infarctions, MI
- Coronary Artery Bypass Graft: CABG
- Uncontrolled Hypertension
- Congestive Heart Failure (CHF) NYHA II-IV

REPORTING OF SUSPECTED ADVERSE REACTIONS:
To allow continued monitoring of the benefit / risk balance of the medicinal product, reporting of suspected adverse reactions is necessary. Healthcare professionals are encouraged to report any suspected adverse reactions directly to the importer / distributor and / or to FDA: www.fda.gov.ph

Patients are advised to seek immediate medical attention, at the first sign/s of adverse reactions.

ADVERSE EFFECTS:
Hypersensitivity reactions including anaphylaxis and angioedema have occurred in patients receiving etoricoxib ; it should be stopped at the first signs of hypersensitivity.

PRECAUTIONS:
Etoricoxib should be avoided in patients with severe hepatic impairment (child-pugh score of 10 or more). Therapy should be stopped if persistently abnormal liver enzyme values are seen.
Etoricoxib should not be used in patients with ischaemic heart disease, peripheral arterial disease, or cerebrovascular disease. It should be used with caution in patients with significant risk factors for cardiovascular disease such as hypertension, hyperlipidaemia, and diabetes mellitus. 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. Etoricoxib should not be used in patients with hypertension whose blood pressure is not controlled .

DOSAGE AND ADMINISTRATION:
In osteoarthritis, etoricoxib is given orally in a usual dose of 30 mg once daily, increased to 60 mg once daily if necessary. 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 be used for the acute symptomatic period and for a maximum of 8 days. Or as prescribed by the physician.

OVERDOSAGE AND TREATMENT:
In the event of overdose, supportive measures should be done (e. g., remove unabsorbed material from the GI tract, Clinical monitoring)

Etoricoxib is not dialyzable by hemodialysis, no information whether etoricoxib is dialyzable by peritoneal dialysis.

CAUTION:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

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

AVAILABILITY:
Alu/Alu Blister Pack x 10's (Box of 30's).
Alu/Alu Blister Pack x 15's (Box of 30's).

FDA Registration Number : DRP-4719
Date of Renewal of Authorization : 9 May 2018
Date of Revision of Package Insert : 29 January 2022

Manufactured by :
ARISTOPHARMA LTD.
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Imported and Distributed by:
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20002632/04