

Etoricoxib

Starcox[®]

60mg, 90mg and 120mg Film-Coated Tablet
COX-2 Selective Inhibitor



FORMULATION:

Each film-coated tablet contains:
Etoricoxib 60 mg, 90 mg & 120 mg

DESCRIPTION:

Cyclooxygenase (COX) is an enzyme that is responsible for the formation of prostanoids. The three main groups of prostanoids -- prostaglandins (PGs), prostacyclins, and thromboxanes -- each involved in the inflammatory response. There are two, if not three, known types of cyclooxygenase (COX-1, COX-2, and COX-3).

INDICATIONS:

Etoricoxib is used for the treatment of acute gout, inflammatory disease of the joints and osteoarthritis.

PHARMACOLOGICAL PROPERTIES:

COX-2 inhibitors are a class of drugs which selectively inhibit COX-2, an enzyme involved in the inflammation pathway, while sparing COX-1, thereby reducing gastrointestinal toxicity.

Etoricoxib is a COX-2 selective inhibitor. It selectively inhibits isoform 2 of cyclooxygenase enzyme (COX-2). This reduces the generation of prostaglandins (PGs) from arachidonic acid. Among the different functions exerted by PGs, their role in the inflammation cascade should be highlighted. COX-2 selective inhibitor (aka "COXIB") showed less marked activity on type 1 cyclooxygenase compared to traditional non-steroidal anti-inflammatory drugs (NSAIDs).

DOSE AND ADMINISTRATION:

The usual dose for chronic pain is 60 mg to 90 mg daily or as prescribed by the physician.

The usual dose for acute pain is 120 mg daily 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) NYHA II-IV

PRECAUTIONS:

Etoricoxib should be used with caution to patients with renal and hepatic impairment. It should not be used by pregnant and breastfeeding patients, patients with severe heart failure and those with active peptic ulcer.

Etoricoxib should not be taken with any other non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen, diclofenac or pain-relieving doses of aspirin, as this may increase the risk of side effects on the stomach and intestines.

- a. COX-2 inhibitors are not to be given to patients with allergy to NSAIDs and those with asthma.
- b. Exercise caution when prescribing selective COX-2 inhibitors in patients with ischemic heart disease and those with risk factors for heart disease; hypertension; hyperlipidemia, diabetes, smoking and patients with peripheral arterial disease.
- c. 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.
- d. Intake of COX-2 inhibitors should be stopped with appearance of skin rash and signs of hypersensitivity.
- e. If not yet instituted, warning statement should include potential gastrointestinal (gastric and liver) and renal toxicities.

ADVERSE EFFECTS:

The most common adverse effects in using etoricoxib include headache, rashes, blurred vision, difficulty in sleeping (insomnia), muscle cramps, fatigue, disturbances of the gut such as diarrhoea, constipation, nausea, vomiting or abdominal pain, weight gain, ulceration of the stomach or intestine, cold or flu-like symptoms, dizziness, excessive fluid retention in the body tissues, resulting in swelling (edema), nosebleeds (epistaxis), difficulty in breathing (dyspnoea), weakness or loss of strength (asthenia), high blood pressure (hypertension), chest pain, anxiety and liver or kidney disorders.

CAUTION:

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

STORAGE CONDITION:

Store at temperatures not exceeding 30°C.

AVAILABILITY:

60 mg Film Coated Tablet FDA REG. NO.: DR-XY39310
90 mg Film Coated Tablet FDA REG. NO.: DR-XY41178
120 mg Film Coated Tablet FDA REG. NO.: DR-XY39309
Alu-Alu Blister Pack x 10's (Box of 30's)

"For suspected adverse drug reaction, report to the FDA: www.fda.gov/ph"

Seek medical attention immediately at the first sign of any adverse drug reaction.

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