Etostar

Etoricoxib INN Tablet

Composition
Etostar 90 Tablet: Each film coated tablet contains Etoricoxib INN 90 mg.
Etostar 120 Tablet: Each film coated tablet contains Etoricoxib INN 120 mg.

Pharmacology
It is a nonsteroidal anti-inflammatory drug (NSAID) that exhibits anti-inflammatory, analgesic, and antipyretic activities in animal models. It is a potent, orally active, highly selective cyclooxygenase-2 (COX-2) inhibitor within and above the clinical dose range. COX-2 has been shown to be primarily responsible for the synthesis of prostanoid mediators of pain, inflammation, and fever. Selective inhibition of COX-2 by Etoricoxib decreases these clinical signs and symptoms with decreased GI toxicity and without effects on platelet function.

Indication
Etoricoxib is indicated for the relief of pain and inflammation in-

- Osteoarthritis
- Rheumatoid arthritis
- Other chronic musculoskeletal disorders
- Acute gout
- Dysmenorrhoea &
- Following dental surgery

Dose and Administration
a) Route of administration: Oral
Adult and adolescent over 16 years:
Osteoarthritis: The recommended dose is 30 mg once a day, increase to a maximum of 60 mg once a day if needed.
Rheumatoid arthritis: The recommended dose is 60 mg once a day, increased to a maximum of 90 mg once a day if needed.
Ankylosing spondylitis: The recommended dose is 60 mg once a day, increased to a maximum of 90 mg once a day if needed.
Acute gout: The recommended dose is 120 mg once a day which should only be used for the acute painful period, limited to a maximum of 8 days treatment.
Postoperative dental surgery pain: The recommended dose is 90 mg once daily, limited to a maximum of 3 days treatment.

Contraindication
It is contra-indicated in patients with hypersensitivity to any component of this product, patients with inflammatory bowel disease, severe congestive heart failure.

Warning & Precaution
In patients with advanced renal disease, treatment with it is not recommended. Clinical experience in patients with estimated creatinine clearance of <30 ml/min is very limited. If therapy with it must be initiated in such patients, close monitoring of the patient's renal function is advisable. Caution should be used when initiating treatment with it in patients with considerable dehydration. It is advisable to rehydrate patients prior to starting therapy with it. The possibility of fluid retention, oedema or hypertension should be taken into consideration when it is used in patients with pre-existing oedema, hypertension, or heart failure. Independent of treatment, patients with a prior history of GI perforation, ulcers and bleeding (PUB) and patients greater than 65 years of age are known to be at a higher risk for a PUB. A patient with symptoms and/or signs suggesting liver dysfunction, or in whom an abnormal liver function test has occurred, should be evaluated for persistently abnormal liver function tests. If persistently abnormal liver function tests (three times the upper limit of normal) are detected, it should be discontinued. It should be used with caution in patients who have previously experienced acute asthmatic attacks, urticaria or rhinitis, which were precipitated by salicylates or non-selective cyclooxygenase inhibitors. It may mask fever, which is a sign of infection. The physician should be aware of this when using it in patients being treated for infection.

Side-Effects
a) Common: Common side effects of etoricoxib are headache, muscle cramps, dry mouth, taste disturbance, mouth ulcers, flatulence, constipation, appetite and weight changes, chest pain fatigue and influenza.
b) Rare: Hepatic failure, jaundice, facial oedema and urticaria.

Use in Pregnancy & Lactation
Pregnancy: Etoricoxib tablets must not be taken during pregnancy. It should be used during upto second trimesters of pregnancy only if the potential benefit justifies the potential risk to the fetus.
Lactation: It is not known whether this drug is excreted in human milk.

Use in Children and adolescents
It is not recommended for children and adolescents. It can be given adults and adolescents over 16 years.

Drug Interaction
a) With Medicine: The metabolism of Etoricoxib can be increased when combined with Abatacept. The serum concentration of Etoricoxib can be increased when it is combined with Abiraterone. The metabolism of Acalabrutinib can be decreased when combined with Etoricoxib. The risk or severity of adverse effects can be increased when Etoricoxib is combined with Aceclofenac. The risk or severity of adverse effects can be increased when Etoricoxib is combined with Acemetacin.
b) With Food and Other: Take with or without food. The absorption is unaffected by the food.

Overdose
No over dose of Etoricoxib were reported during clinical trials. In clinical studies, administration of a single dose of Etoricoxib up to 500 mg and multiple doses up to 150 mg/day for 21 days did not result in significant toxicity.

Storage
Store below 30°C. Protect from light and moisture. Keep all medicines out of reach of children.

Packing
Etostar 90 Tablet: Each box contains 30 (3x10's) Tablets in Blister Pack.
Etostar 120 Tablet: Each box contains 20 (2x10's) Tablets in Blister Pack.

Manufactured by
ONE PHARMA LTD.
C-23-24, BSCIC I/A
Bogura, Bangladesh

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