

Composition:

Each Coxi (60-90-120) Film Coated Tablet contains:

Etoricoxib (60-90-120) mg.

Pharmacological Properties & Mechanism of Action:

Etoricoxib is a NSAID that possesses anti-inflammatory, analgesic and antipyretic activity. It is a potent and selective inhibitor of cyclooxygenase-2 (COX-2) in doses up to 150 mg per day, which leads to a marked decrease in the synthesis of prostaglandins, it does not inhibit the synthesis of prostaglandins in the stomach and it has no effect on platelet function.

Pharmacokinetics:

Orally administered etoricoxib is well absorbed. The absolute bioavailability is approximately 100%. Peak plasma concentrations occurring 1 hour after administration of 120 mg. It is approximately 92% bound to human plasma protein. About 70% of administered was excreted in urine and 20% in faeces, mostly as metabolites, Less than 2% of the drug is excreted unchanged.

Indications:

Coxi is indicated in the following cases:

- Rheumatoid arthritis.
- Acute and chronic treatment of the signs and symptoms of osteoarthritis.
- Ankylosing spondylitis.
- Chronic musculoskeletal pain.
- Acute gouty arthritis.
- Relief of acute pain after dental surgery.
- Degenerative arthritis.

Contraindications:

Coxi is contraindicated in patients with:

- Hypersensitivity to the active substance or to any of the components of the preparation.
- Previous hypersensitivity reactions (e.g. asthma, urticaria, angioedema or rhinitis) after taking aspirin or other NSAIDs.
- Active peptic ulceration or active gastro-intestinal (GI) bleeding.
- Severe heart failure (NYHA II-IV), severe hepatic failure and renal failure.
- Established ischemic heart disease, peripheral arterial disease, and/or cerebrovascular disease.
- an creatinine clearance < 30 ml/min.

Warnings & Precautions:

- Caution is advised with treatment of patients most at risk of developing a gastrointestinal complication with NSAIDs.
- Caution should be exercised in patients with a history of heart

failure, left ventricular dysfunction or hypertension and in patients with preexisting oedema from any other reason.

- Renal function should be monitored in patients with renal failure.

- If signs of hepatic insufficiency appear, or if abnormal liver tests are observed for a prolonged period (three times the upper limit of normal), Etoricoxib should be discontinued.

- Caution should be exercised when initiating etoricoxib in patients who are dehydrated. It is recommended that patients be given adequate fluids before starting treatment with Coxi.

- Caution should be exercised when using Coxi in patients with hypertension, hyperlipidemia, and diabetes mellitus.

Pregnancy & Lactation:

Pregnancy: Pregnancy category C. Etoricoxib should not be used during the first and second trimesters of pregnancy unless the potential benefit outweighs the potential risk to the fetus and is contraindicated during the third trimester.

Lactation: It is not known if etoricoxib is excreted in mother milk. Women using etoricoxib should stop breastfeeding during treatment.

Drug Interactions:

- Concomitant use of etoricoxib 120 mg daily with warfarin may cause an increase in prothrombin time by up to 13%.

- Concomitant administration of diuretics, ACE inhibitors and angiotensin II antagonists with etoricoxib may reduce the anti-hypertensive effect of these drugs.

- Cyclosporine and tacrolimus: Co administration may increase the risk of nephrotoxicity.

- Methotrexate: Etoricoxib may reduce the renal clearance of methotrexate. Toxicity associated with methotrexate should be monitored when etoricoxib in doses greater than 90 mg daily is concomitantly administered.

- Lithium: NSAIDs and selective COX-2 inhibitors may increase plasma lithium levels. This interaction should be considered in patients taking etoricoxib concomitantly with lithium.

- Concomitant use of Coxi with oral contraceptives leads to an increase in the plasma concentration of ethinyl estradiol.

- Co administration of etoricoxib with rifampicin results in a 65% decrease in plasma concentrations of etoricoxib.

Side Effects:

The most noticeable side effects were:

Anemia, (primarily associated with gastrointestinal bleeding), leukopenia, thrombocytopenia, alveolar osteitis, angioedema, appetite increase or decrease, weight gain, anxiety, dizziness, headache, insomnia, arrhythmia, blurred vision, bronchospasm, cough, abdominal pain and flatulence, constipation, gastritis, heartburn, dyspepsia, dry mouth, peptic ulcers, ALT increased,

AST increased, ecchymosis, Muscle pain and spasm, asthenia, fatigue, and chest pain.

Driving & Using Machines:

Patients who experience dizziness, vertigo or somnolence while taking etoricoxib should refrain from driving or operating machinery.

Dosage & Administration:

Coxi is taken by mouth with or without food.

Coxi is indicated in adolescents over 16 years of age and adults for symptomatic treatment in the following cases:

- Osteoarthritis: 30 or 60 mg once daily.

- Rheumatoid arthritis: 60 or 90 mg once daily*.

- Ankylosing spondylitis: 60 or 90 mg once daily*.

- Acute gouty arthritis: 120 mg once daily, for a maximum of 8 day

- Post-operative dental pain: 90 mg once daily, for a maximum of 3 days.

- Acute pain: 120 mg once daily, for a maximum of 8 days.

- Chronic musculoskeletal pain: The recommended dose is 60 mg once daily.

*Once the patient is clinically stabilized, down-titration to a 60 mg once daily dose may be appropriate.

Overdose:**Symptoms:**

Administration of single doses of up to 500 mg of Etoricoxib or multiple doses of up to 150 mg/day for 21 days did not result in significant toxicity (the most common side effects that may result from an overdose of etoricoxib are gastrointestinal disorders and cardiovascular disorders).

Treatment:

In the event of overdosage, usual supportive measures may be used, e.g., removal of unabsorbed material from the gastrointestinal tract, clinical monitoring, and initiation of supportive therapy, if necessary. Etoricoxib cannot be removed by hemodialysis.

Storage:

Keep out of reach of children. Store below 25 °C.

Packaging:

Each Coxi (60-90) carton box contains 20 Film Coated Tablets in two blister strips.

Each Coxi 120 carton box contains 10 Film Coated Tablets in a blister strip.

