Millimed

เอกสารกำกับยาภาษาอังกฤษ

(เหมือนกันทุกขนาดบรรจุ)

ETOCOX

Etoricoxib film coated tablets

Name and strength of active ingredient :

Each film coated tablet contains :-

Name	Strength of active ingredient
ETOCOX 60	Etoricoxib 60 mg
ETOCOX 90	Etoricoxib 90 mg
ETOCOX 120	Etoricoxib 120 mg

Product description :

- ETOCOX 60 : Pale green, round, biconvex film coated tablet, plain on both sides.
- ETOCOX 90 : White, round, biconvex film coated tablet, plain on both sides.
- ETOCOX 120 : Green, round, biconvex film coated tablet, plain on one side and score on the other.

Pharmacodynamics :

(เอกสารอ้างอิง 1: Martindale The Complete Drug Reference, 38th edition (2014) p. 57 หัวข้อ (1) Etoricoxib/ Uses and Administration)

(เอกสารอ้างอิง 2: Basic and Clinical Pharmacology 12th edition (2012) p. 640 หัวข้อ (1) Chapter 36 Nonsteriodal Anti-inflammationtory Drugs, Disease Modifying Antirheumatic Drugs, Nonopioid Analgesics, & Drugs Used in Gout/ COX-2 SELECTIVE INHIBITORS)

Etoricoxib is a non-steroidal anti-inflammatory drug (NSAID), selective inhibitor of cyclooxygenase-2 (COX-2), it can inhibit prostaglandin synthesis by the inhibition of COX-2 isozyme induced at sites of inflammation without inhibition of COX-1 isozyme found in the GI tract, kidneys, and platelets. Etoricoxib selectively binds to and block the active site of the COX-2 enzyme much more effectively than that of COX-1. Etoricoxib has analgesic, antipyretic and anti-inflammatory effects similar to those of non-selective NSAIDs but with an approximate halving of GI adverse effects. Likewise, etoricoxib at usual dose have no impact on platelet aggregation which is mediated by thromboxane produced by the COX-1 isozyme.

Pharmacokinetics :

(เอกสารอ้างอิง 1: Martindale The Complete Drug Reference, 38th edition (2014) p. 58 หัวข้อ (1) Etoricoxib/ 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 isozymes including CYP 3A4 to form the 6'-hydroxymethyl derivative of etoricoxib, which is then oxidized to the 6'-carboxylic acid derivative, the major metabolite. Excretion is mainly via the urine (70%) with only 20% of a dose appearing in feces.

Indications :

(เอกสารอ้างอิง 1: Martindale The Complete Drug Reference, 38th edition (2014) p. 57 หัวข้อ (2) Etoricoxib/ Uses and Administration)

(เอกสารอ้างอิง 3: เอกสารกำกับยา ARCOXIA® หัวข้อ (2) INDICATIONS)

(เอกสารอ้างอิง 4) British National Formulary (BNF) 68th edition (2014) p. 703 หัวข้อ (2) Non-steroidal anti-inflammatory drugs/Choice, Dental and orofacial pain)

ETOCOX is indicated for symptomatic treatment of osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, acute gouty arthritis, primary dysmenorrhea, post-operative dental pain, post-operative gynecological pain and chronic musculoskeletal pain, including chronic low back pain.

Recommended Dose :

(เอกสารอ้างอิง 1: Martindale The Complete Drug Reference, 38th edition (2014) p. 57 หัวข้อ (3) Etoricoxib/ Uses and Administration)

(เอกสารอ้างอิง 3: เอกสารกำกับยา ARCOXIA® หัวข้อ (3) DOSAGE AND ADMINISTRATION)

***Osteoarthritis*:** 30 mg or 60 mg once daily

***Rheumatoid arthritis*:** 90 mg once daily

***Ankylosing spondylitis*:** 90 mg once daily

Chronic musculoskeletal pain, including chronic low back pain: 60 mg once daily

***Acute gouty arthritis*:** 120 mg once daily

***Primary Dysmenorrhea*:** 120 mg once daily

***Post-operative Dental Pain*:** 90 mg once daily

***Post-operative Gynecological Pain*:** 90 mg once daily; the initial dose should be administered shortly before surgery. The dose can be increased to a maximum 120 mg once daily.

For acute pain conditions, it should be used only for the acute symptomatic period limit to a maximum of 8 days.

***Hepatic Insufficiency*:**

- In patients with mild hepatic insufficiency (Child-Pugh score 5-6), the maximum oral dose of etoricoxib, regardless of indications is 60 mg once daily.

- In patients with moderate hepatic insufficiency (Child-Pugh score 7-9) should be given a maximum of 60 mg every other day or 30 mg once daily.

- There are no data in patients with severe hepatic insufficiency (Child-Pugh score > 9), etoricoxib should not be given to patients with severe hepatic insufficiency.

Renal Insufficiency:

- In patients with advanced renal disease (creatinine clearance < 30 mL/min), treatment with etoricoxib is not recommended.

-In patients with lesser degrees of renal insufficiency (creatinine clearance ≥ 30 mL/min), no dosage adjustment is necessary.

Mode of Administration :

(เอกสารอ้างอิง 3: เอกสารกำกับยา ARCOXIA® หัวข้อ (4) DOSAGE AND ADMINISTRATION)

Etoricoxib is administered orally. It may be taken with or without food. It should be administered for the shortest duration possible and the lowest effective daily dose should be used.

Contraindications :

(เอกสารอ้างอิง 1: Martindale The Complete Drug Reference, 38th edition (2014) p. 57-58 หัวข้อ (5) Etoricoxib/ Adverse Effects, Treatment, and Precautions)

(เอกสารอ้างอิง 4) British National Formulary (BNF) 68th edition (2014) p. 703 หัวข้อ (5) Non-steroidal anti-inflammatory drugs/Cautions and contra-indication)

(เอกสารอ้างอิง 4) British National Formulary (BNF) 68th edition (2014) p. 707 หัวข้อ (5) Etoricoxib/Contra-indication)

- Patients with known hypersensitivity to any component of this product
- Patients with moderate to severe heart failure (NYHA class II-IV)
- Patients with inadequately controlled hypertension
- Patients with ischemic heart disease

- Patients with peripheral arterial disease and/or cerebrovascular disease
- Patients with active peptic ulceration or GI bleeding
- Patients with renal impairment (Creatinine clearance < 30 mL/min)
- Patients with severe hepatic insufficiency (Child-Pugh score > 9)
- Patients with inflammatory bowel disease

Warnings:

(เอกสารอ้างอิง 5: ประกาศกระทรวงสาธารณสุข เรื่อง ยาที่ต้องแจ้งคำเตือนการใช้ยาไว้ในฉลากและที่เอกสารกำกับยาและข้อความของคำเตือน)

1. Contraindicate in patients with known hypersensitivity to any component of this product, pregnancy and lactation.
2. Contraindicate in patients who have recently undergone coronary artery bypass graft surgery (immediately postoperative period).
3. Contraindicate in patients with cardiovascular and cerebrovascular disease.
4. Contraindicate in patients with un-controlled hypertension.
5. Contraindicate in patients with myocardial infarction or congestive heart failure (NYHA II-IV).
6. Contraindicate in patients with history of ischemic heart disease or history of paralysis from cerebrovascular disease.
7. Caution should be used in patients with risk factors of cardiovascular disease such as hypertension, hyperlipidemia, diabetes mellitus, smoking and elderly.
8. Caution should be used in patients with hepatic and renal impairment.

Precautions :

(เอกสารอ้างอิง 1: Martindale The Complete Drug Reference, 38th edition (2014) p. 57-58 หัวข้อ (6) Etoricoxib/ Adverse Effects, Treatment, and Precautions)

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

Etoricoxib should not be used in patients with ischemic heart disease, peripheral arterial disease, or cerebrovascular disease. It should be used with caution in patients with significant risk factor for cardiovascular disease such as hypertension, hyperlipidemia, and diabetes mellitus.

Etoricoxib, particularly at high doses, may be associated with frequent and severe hypertension, blood pressure monitoring during etoricoxib treatment is recommended. Etoricoxib should not be used in patients with hypertension whose blood pressure is not controlled.

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Etoricoxib may cause less gastrotoxicity than that seen with the non-selective inhibition of the traditional NSAIDs. However, it should be used with caution in patients with history or at risk of gastrointestinal ulceration and bleeds.

Etoricoxib should be avoided in patients with severe hepatic impairment. Therapy should be stopped if persistently abnormal liver enzyme values are seen.

Caution is recommended when using etoricoxib in dehydrated patients; it may be advisable to rehydrate patients before giving etoricoxib.

Interactions with other medicaments :

(เอกสารอ้างอิง 1: Martindale The Complete Drug Reference, 38th edition (2014) p. 58 หัวข้อ (7) Etoricoxib/ Interactions)

(เอกสารอ้างอิง 1: Martindale The Complete Drug Reference, 38th edition (2014) p. 107-108 หัวข้อ (7) Nonsteriodal Anti-inflammatory Drugs/Interactions)

The metabolism of etoricoxib is mediated by the cytochrome P450 isozymes CYP3A4. Use with other drugs that inhibit or induce this isoenzyme may result in changes in plasma concentration 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 a possibility.

Interactions involving NSAIDs include enhancement of the effects of oral anticoagulants and increased plasma concentrations of lithium, methotrexate, and cardiac glycosides.

The risk of nephrotoxicity may be increased if given with ACE inhibitors, Ciclosporin, Tacrolimus, or diuretics. Effects on renal function may lead to reduced excretion of some drugs. There may also be an increased risk of hyperkalemia with ACE inhibitors and some diuretics, including potassium sparing diuretics.

Use of more than one NSAIDs together (including aspirin) should be avoided because of the increased risk of adverse effects. The risk of gastrointestinal bleeding and ulceration associated with NSAIDs is increased when used with corticosteroids, the SSRIs, the SNRI (venlafaxine), the antiplatelets (clopidogrel and ticlopidine), iloprost, erlotinib, sibutramine, or, possibly, alcohol, bisphosphonates, or pentoxifylline.

Pregnancy and Lactation :

(เอกสารอ้างอิง 4) British National Formulary (BNF) 68th edition (2014) p. 703-704 หัวข้อ (8) Non-steroidal anti-inflammatory drugs/Pregnancy, Breast-feeding)

(เอกสารอ้างอิง 4) British National Formulary (BNF) 68th edition (2014) p. 707 หัวข้อ (8) ETORICOXIB/ Pregnancy, Breast-feeding)

Pregnancy: Avoid the use of etoricoxib during pregnancy or avoiding them unless the potential benefit outweighs the risk. It should be avoided during the third trimester because use is associated with a risk of closure of fetal ductus arteriosus in utero and possibly persistent pulmonary hypertension of the newborn. In addition, the onset of labour may be delayed and its duration may be increase.

Lactation: Etoricoxib should be avoided during breast-feeding because it is presented in milk in animal studies.

Undesirable effects :

(เอกสารอ้างอิง 4) British National Formulary (BNF) 68th edition (2014) p. 704 หัวข้อ (9) Non-steroidal anti-inflammatory drugs/Side-effects)

(เอกสารอ้างอิง 4) British National Formulary (BNF) 68th edition (2014) p. 707 หัวข้อ (9) ETORICOXIB/Side-effects)

Gastrointestinal: Discomfort, nausea, diarrhea, bleeding, ulceration

CNS: Headache, dizziness, nervousness, depression, drowsiness, insomnia, vertigo, anxiety, mental acuity impaired, paraesthesia, confusion, hallucinations

Cardiovascular: Hypertension, palpitation, atrial fibrillation, transient ischemic attack, chest pain,

Respiratory: cough, dyspnea, epistaxis

Renal: Renal failure

Hepatic: Hepatic damage

Hypersensitivity reactions: Rashes, angioedema, bronchospasm

Others: Fluid retention, hearing disturbances (tinnitus), visual disturbance, photosensitivity, haematuria, fatigue, myalgia, arthralgia, influenza-like symptoms, ecchymosis, dry mouth, taste disturbance, mouth ulcer, appetite, weight change, flushing, electrolyte disturbance

Overdose and treatment :

(เอกสารอ้างอิง 1: Martindale The Complete Drug Reference, 38th edition (2014) p. 107 หัวข้อ (10) Nonsteriodal Anti-inflammatory Drugs/Overdosage)

Symptoms: Nausea, vomiting, epigastric pain, tinnitus, headache, drowsiness, blurred vision, dizziness and gastrointestinal bleeding

Treatment: Treatment of NSAID overdosage is entirely supportive. The benefit of gastric decontamination is uncertain although activated charcoal may be of benefit within 1 hour of ingestion of a potentially toxic amount. Force diuresis, hemodialysis, or hemoperfusion are likely to be of benefit for NSAID overdosage, although hemodialysis may be required if oligouric renal failure develops.

Storage condition :

(อ้างอิง : 3.2P.8.3 Stability data)

Store below 30°C.

Dosage Forms and Packaging Available :

Film coated tablets are filled in aluminium - aluminium blister pack of 5 and 10 tablets packed in paper box of 3, 5, 10 and 50 packs.

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