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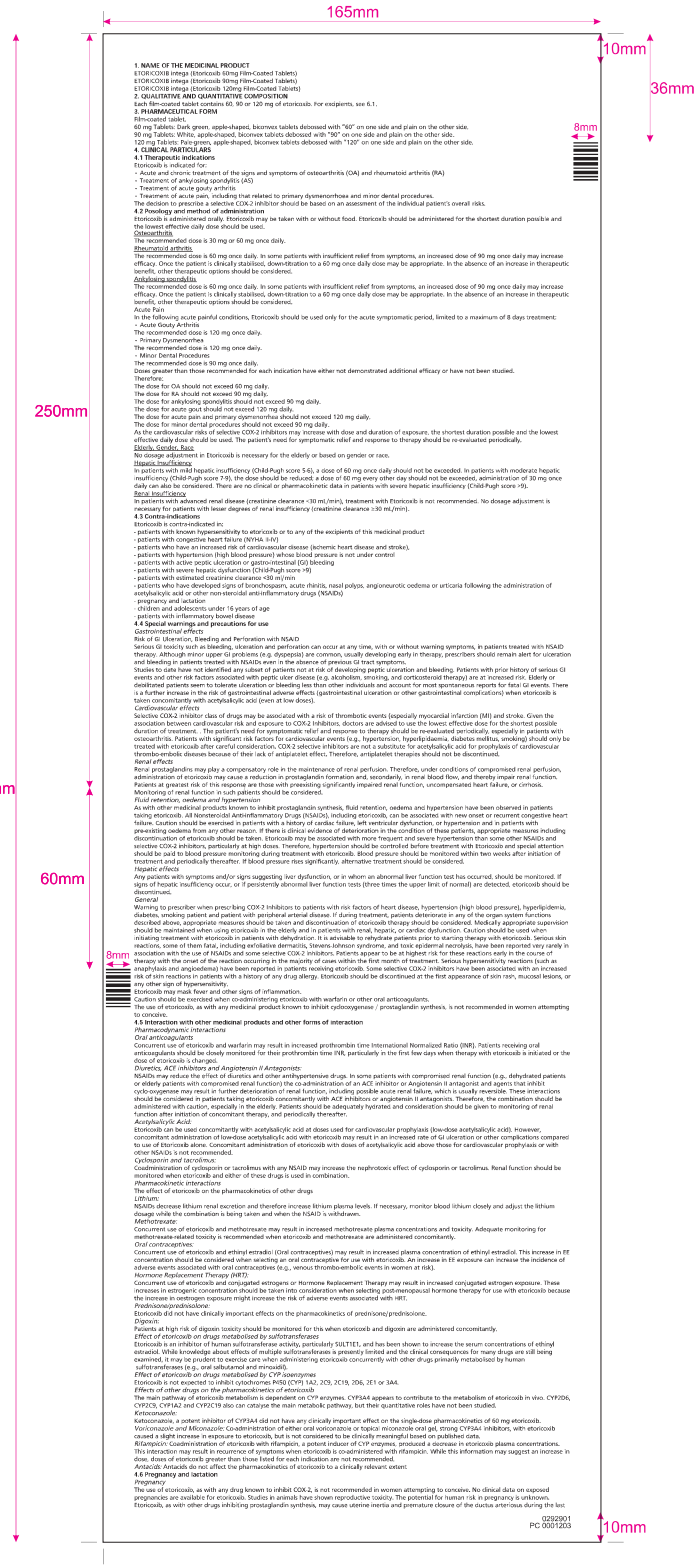
PIL ETORICOXIB INTEGA MY
Code: 0292901
Pharmacode: PC0001203



1. NAME OF THE MEDICINAL PRODUCT
ETORICOXIB Intega (Etoricoxib 60mg Film-Coated Tablets)
ETORICOXIB Intega (Etoricoxib 90mg Film-Coated Tablets)
ETORICOXIB Intega (Etoricoxib 120mg Film-Coated Tablets)
2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each film-coated tablet contains 60, 90 or 120 mg of etoricoxib. For excipients, see 6.1.
3. PHARMACEUTICAL FORM
Film-coated tablet.
60 mg Tablets: Dark green, apple-shaped, biconvex tablets debossed with "60" on one side and plain on the other side.
90 mg Tablets: White, apple-shaped, biconvex tablets debossed with "90" on one side and plain on the other side.
120 mg Tablets: Pale-green, apple-shaped, biconvex tablets debossed with "120" on one side and plain on the other side.
4. CLINICAL PARTICULARS
4.1 Therapeutic indications
Etoricoxib is indicated for:
- Acute and chronic treatment of the signs and symptoms of osteoarthritis (OA) and rheumatoid arthritis (RA)
- Treatment of ankylosing spondylitis (AS)
- Treatment of acute gouty arthritis
- Treatment of acute pain, including that related to primary dysmenorrhoea and minor dental procedures.

The decision to prescribe a selective COX-2 inhibitor should be based on an assessment of the individual patient's overall risks.
4.2 Posology and method of administration
Etoricoxib is administered orally. Etoricoxib may be taken with or without food. Etoricoxib should be administered for the shortest duration possible and the lowest effective daily dose should be used.
Osteoarthritis
The recommended dose is 30 mg or 60 mg once daily.
Rheumatoid arthritis
The recommended dose is 60 mg once daily. In some patients with insufficient relief from symptoms, an increased dose of 90 mg once daily may increase efficacy. Once the patient is clinically stabilised, down-titration to a 60 mg once daily dose may be appropriate. In the absence of an increase in therapeutic benefit, other therapeutic options should be considered.
Ankylosing spondylitis
The recommended dose is 60 mg once daily. In some patients with insufficient relief from symptoms, an increased dose of 90 mg once daily may increase efficacy. Once the patient is clinically stabilised, down-titration to a 60 mg once daily dose may be appropriate. In the absence of an increase in therapeutic benefit, other therapeutic options should be considered.
Acute Pain
In the following acute painful conditions, Etoricoxib should be used only for the acute symptomatic period, limited to a maximum of 8 days treatment:
- Acute Gouty Arthritis

The recommended dose is 120 mg once daily.
- Primary Dysmenorrhea

The recommended dose is 120 mg once daily.
- Minor Dental Procedures

The recommended dose is 90 mg once daily.
Doses greater than those recommended for each indication have either not demonstrated additional efficacy or have not been studied.
Therefore:
The dose for OA should not exceed 60 mg daily.
The dose for RA should not exceed 90 mg daily.
The dose for ankylosing spondylitis should not exceed 90 mg daily.
The dose for acute gout should not exceed 120 mg daily.
The dose for acute pain and primary dysmenorrhea should not exceed 120 mg daily.
The dose for minor dental procedures should not exceed 90 mg daily.
As the cardiovascular risks of selective COX-2 inhibitors may increase with dose and duration of exposure, the shortest duration possible and the lowest effective daily dose should be used. The patient's need for symptomatic relief and response to therapy should be re-evaluated periodically.
Elderly, Gender, Race
No dosage adjustment in Etoricoxib is necessary for the elderly or based on gender or race.
Hepatic Insufficiency
In patients with mild hepatic insufficiency (Child-Pugh score 5-6), a dose of 60 mg once daily should not be exceeded. In patients with moderate hepatic insufficiency (Child-Pugh score 7-9), the dose should be reduced; a dose of 60 mg every other day should not be exceeded, administration of 30 mg once daily can also be considered. There are no clinical or pharmacokinetic data in patients with severe hepatic insufficiency (Child-Pugh score >9).
Renal Insufficiency
In patients with advanced renal disease (creatinine clearance <30 mL/min), treatment with Etoricoxib is not recommended. No dosage adjustment is necessary for patients with lesser degrees of renal insufficiency (creatinine clearance ≥30 mL/min).
4.3 Contra-indications
Etoricoxib is contra-indicated in:
- patients with known hypersensitivity to etoricoxib or to any of the excipients of this medicinal product
- patients with congestive heart failure (NYHA II-IV)
- patients who have an increased risk of cardiovascular disease (ischemic heart disease and stroke),
- patients with hypertension (high blood pressure) whose blood pressure is not under control
- patients with active peptic ulceration or gastro-intestinal (GI) bleeding
- patients with severe hepatic dysfunction (Child-Pugh score >9)
- patients with estimated creatinine clearance <30 ml/min
- patients who have developed signs of bronchospasm, acute rhinitis, nasal polyps, angioneurotic oedema or urticaria following the administration of acetylsalicylic acid or other non-steroidal anti-inflammatory drugs (NSAIDs)
- pregnancy and lactation
- children and adolescents under 16 years of age
- patients with inflammatory bowel disease

4.4 Special warnings and precautions for use
Gastrointestinal effects
Risk of GI Ulceration, Bleeding and Perforation with NSAID
Serious GI toxicity such as bleeding, ulceration and perforation can occur at any time, with or without warning symptoms, in patients treated with NSAID therapy. Although minor upper GI problems (e.g. dyspepsia) are common, usually developing early in therapy, prescribers should remain alert for ulceration and bleeding in patients treated with NSAIDs even in the absence of previous GI tract symptoms.
Studies to date have not identified any subset of patients not at risk of developing peptic ulceration and bleeding. Patients with prior history of serious GI events and other risk factors associated with peptic ulcer disease (e.g. alcoholism, smoking, and corticosteroid therapy) are at increased risk. Elderly or debilitated patients seem to tolerate ulceration or bleeding less than other individuals and account for most spontaneous reports for fatal GI events. There is a further increase in the risk of gastrointestinal adverse effects (gastrointestinal ulceration or other gastrointestinal complications) when etoricoxib is taken concomitantly with acetylsalicylic acid (even at low doses).
Cardiovascular effects
Selective COX-2 inhibitor class of drugs may be associated with a risk of thrombotic events (especially myocardial infarction (MI) and stroke. Given the association between cardiovascular risk and exposure to COX-2 inhibitors, doctors are advised to use the lowest effective dose for the shortest possible duration of treatment. The patient's need for symptomatic relief and response to therapy should be re-evaluated periodically, especially in patients with osteoarthritis. Patients with significant risk factors for cardiovascular events (e.g., hypertension, hyperlipidaemia, diabetes mellitus, smoking) should only be treated with etoricoxib after careful consideration. COX-2 selective inhibitors are not a substitute for acetylsalicylic acid for prophylaxis of cardiovascular thrombo-embolic diseases because of their lack of antiplatelet effect. Therefore, antiplatelet therapies should not be discontinued.
Renal effects
Renal prostaglandins may play a compensatory role in the maintenance of renal perfusion. Therefore, under conditions of compromised renal perfusion, administration of etoricoxib may cause a reduction in prostaglandin formation and, secondarily, in renal blood flow, and thereby impair renal function. Patients at greatest risk of this response are those with preexisting significantly impaired renal function, uncompensated heart failure, or cirrhosis. Monitoring of renal function in such patients should be considered.
Fluid retention, oedema and hypertension
As with other medicinal products known to inhibit prostaglandin synthesis, fluid retention, oedema and hypertension have been observed in patients taking etoricoxib. All Nonsteroidal Antiinflammatory Drugs (NSAIDs), including etoricoxib, can be associated with new onset or recurrent congestive heart failure. Caution should be exercised in patients with a history of cardiac failure, left ventricular dysfunction, or hypertension and in patients with pre-existing oedema from any other reason. If there is clinical evidence of deterioration in the condition of these patients, appropriate measures including discontinuation of etoricoxib should be taken. Etoricoxib may be associated with more frequent and severe hypertension than some other NSAIDs and selective COX-2 inhibitors, particularly at high doses. Therefore, hypertension should be controlled before treatment with Etoricoxib and special attention should be paid to blood pressure monitoring during treatment with etoricoxib. Blood pressure should be monitored within two weeks after initiation of treatment and periodically thereafter. If blood pressure rises significantly, alternative treatment should be considered.
Hepatic effects
Any patients with symptoms and/or signs suggesting liver dysfunction, or in whom an abnormal liver function test has occurred, should be monitored. If signs of hepatic insufficiency occur, or if persistently abnormal liver function tests (three times the upper limit of normal) are detected, etoricoxib should be discontinued.
General
Warning to prescriber when prescribing COX-2 Inhibitors to patients with risk factors of heart disease, hypertension (high blood pressure), hyperlipidemia, diabetes, smoking patient and patient with peripheral arterial disease. If during treatment, patients deteriorate in any of the organ system functions described above, appropriate measures should be taken and discontinuation of etoricoxib therapy should be considered. Medically appropriate supervision should be maintained when using etoricoxib in the elderly and in patients with renal, hepatic, or cardiac dysfunction. Caution should be used when initiating treatment with etoricoxib in patients with dehydration. It is advisable to rehydrate patients prior to starting therapy with etoricoxib. Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis, have been reported very rarely in association with the use of NSAIDs and some selective COX-2 inhibitors. Patients appear to be at highest risk for these reactions early in the course of therapy with the onset of the reaction occurring in the majority of cases within the first month of treatment. Serious hypersensitivity reactions (such as anaphylaxis and angioedema) have been reported in patients receiving etoricoxib. Some selective COX-2 inhibitors have been associated with an increased risk of skin reactions in patients with a history of any drug allergy. Etoricoxib should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.
Etoricoxib may mask fever and other signs of inflammation.
Caution should be exercised when co-administering etoricoxib with warfarin or other oral anticoagulants.
The use of etoricoxib, as with any medicinal product known to inhibit cyclooxygenase / prostaglandin synthesis, is not recommended in women attempting to conceive.
4.5 Interaction with other medicinal products and other forms of interaction
Pharmacodynamic interactions
Oral anticoagulants
Concurrent use of etoricoxib and warfarin may result in increased prothrombin time International Normalized Ratio (INR). Patients receiving oral anticoagulants should be closely monitored for their prothrombin time INR, particularly in the first few days when therapy with etoricoxib is initiated or the dose of etoricoxib is changed.
Diuretics, ACE inhibitors and Angiotensin II Antagonists:
NSAIDs may reduce the effect of diuretics and other antihypertensive drugs. In some patients with compromised renal function (e.g., dehydrated patients or elderly patients with compromised renal function) the co-administration of an ACE inhibitor or Angiotensin II antagonist and agents that inhibit cyclo-oxygenase may result in further deterioration of renal function, including possible acute renal failure, which is usually reversible. These interactions should be considered in patients taking etoricoxib concomitantly with ACE inhibitors or angiotensin II antagonists. Therefore, the combination should be administered with caution, especially in the elderly. Patients should be adequately hydrated and consideration should be given to monitoring of renal function after initiation of concomitant therapy, and periodically thereafter.
Acetylsalicylic Acid:
Etoricoxib can be used concomitantly with acetylsalicylic acid at doses used for cardiovascular prophylaxis (low-dose acetylsalicylic acid). However, concomitant administration of low-dose acetylsalicylic acid with etoricoxib may result in an increased rate of GI ulceration or other complications compared to use of etoricoxib alone. Concomitant administration of etoricoxib with doses of acetylsalicylic acid above those for cardiovascular prophylaxis or with other NSAIDs is not recommended.
Cyclosporin and tacrolimus:
Coadministration of cyclosporin or tacrolimus with any NSAID may increase the nephrotoxic effect of cyclosporin or tacrolimus. Renal function should be monitored when etoricoxib and either of these drugs is used in combination.
Pharmacokinetic interactions
The effect of etoricoxib on the pharmacokinetics of other drugs
Lithium:
NSAIDs decrease lithium renal excretion and therefore increase lithium plasma levels. If necessary, monitor blood lithium closely and adjust the lithium dosage while the combination is being taken and when the NSAID is withdrawn.
Methotrexate:
Concurrent use of etoricoxib and methotrexate may result in increased methotrexate plasma concentrations and toxicity. Adequate monitoring for methotrexate-related toxicity is recommended when etoricoxib and methotrexate are administered concomitantly.
Oral contraceptives:
Concurrent use of etoricoxib and ethinyl estradiol (Oral contraceptives) may result in increased plasma concentration of ethinyl estradiol. This increase in EE concentration should be considered when selecting an oral contraceptive for use with etoricoxib. An increase in EE exposure can increase the incidence of adverse events associated with oral contraceptives (e.g., venous thrombo-embolic events in women at risk).
Hormone Replacement Therapy (HRT):
Concurrent use of etoricoxib and conjugated estrogens or Hormone Replacement Therapy may result in increased conjugated estrogen exposure. These increases in estrogenic concentration should be taken into consideration when selecting post-menopausal hormone therapy for use with etoricoxib because the increase in estrogen exposure might increase the risk of adverse events associated with HRT.
Prednisone/prednisolone:
Etoricoxib did not have clinically important effects on the pharmacokinetics of prednisone/prednisolone.
Digoxin:
Patients at high risk of digoxin toxicity should be monitored for this when etoricoxib and digoxin are administered concomitantly.
Effect of etoricoxib on drugs metabolised by sulfotransferases
Etoricoxib is an inhibitor of human sulfotransferase activity, particularly SULT1E1, and has been shown to increase the serum concentrations of ethinyl estradiol. While knowledge about effects of multiple sulfotransferases is presently limited and the clinical consequences for many drugs are still being examined, it may be prudent to exercise care when administering etoricoxib concurrently with other drugs primarily metabolised by human sulfotransferases (e.g., oral salbutamol and minoxidil).
Effect of etoricoxib on drugs metabolised by CYP isoenzymes
Etoricoxib is not expected to inhibit cytochromes P450 (CYP) 1A2, 2C9, 2C19, 2D6, 2E1 or 3A4.
Effects of other drugs on the pharmacokinetics of etoricoxib
The main pathway of etoricoxib metabolism is dependent on CYP enzymes. CYP3A4 appears to contribute to the metabolism of etoricoxib in vivo. CYP2D6, CYP2C9, CYP1A2 and CYP2C19 also can catalyse the main metabolic pathway, but their quantitative roles have not been studied.
Ketoconazole:
Ketoconazole, a potent inhibitor of CYP3A4 did not have any clinically important effect on the single-dose pharmacokinetics of 60 mg etoricoxib.
Voriconazole and Miconazole: Co-administration of either oral voriconazole or topical miconazole oral gel, strong CYP3A4 inhibitors, with etoricoxib caused a slight increase in exposure to etoricoxib, but is not considered to be clinically meaningful based on published data.
Rifampicin: Coadministration of etoricoxib with rifampicin, a potent inducer of CYP enzymes, produced a decrease in etoricoxib plasma concentrations. This interaction may result in recurrence of symptoms when etoricoxib is co-administered with rifampicin. While this information may suggest an increase in dose, doses of etoricoxib greater than those listed for each indication are not recommended.
Antacids: Antacids do not affect the pharmacokinetics of etoricoxib to a clinically relevant extent
4.6 Pregnancy and lactation
Pregnancy
The use of etoricoxib, as with any drug known to inhibit COX-2, is not recommended in women attempting to conceive. No clinical data on exposed pregnancies are available for etoricoxib. Studies in animals have shown reproductive toxicity. The potential for human risk in pregnancy is unknown. Etoricoxib, as with other drugs inhibiting prostaglandin synthesis, may cause uterine inertia and premature closure of the ductus arteriosus during the last

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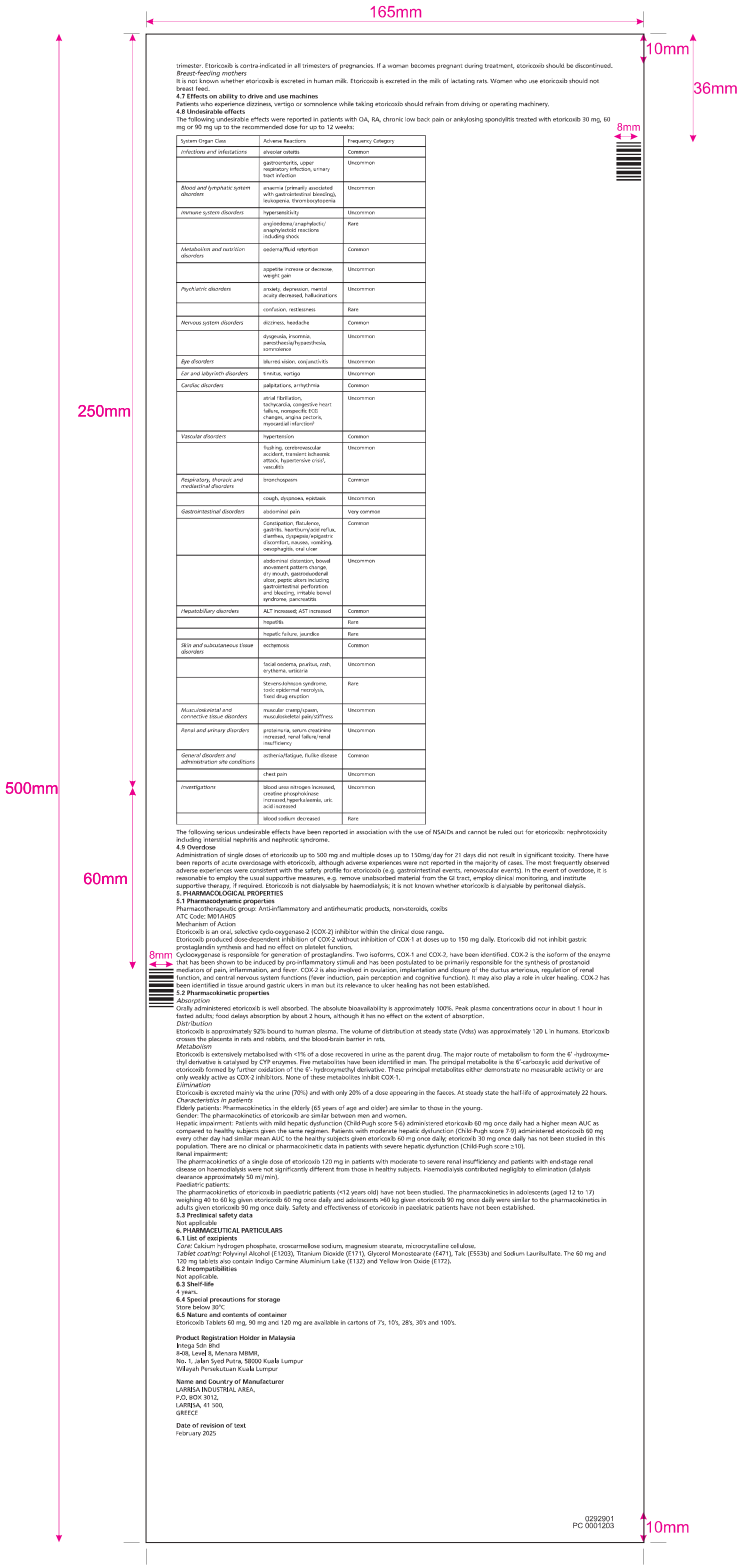

trimester: Etoricoxib is contra-indicated in all trimesters of pregnancies. If a woman becomes pregnant during treatment, etoricoxib should be discontinued.
Breast-feeding mothers
It is not known whether etoricoxib is excreted in human milk. Etoricoxib is excreted in the milk of lactating rats. Women who use etoricoxib should not breast feed.
4.7 Effects on ability to drive and use machines
Patients who experience dizziness, vertigo or somnolence while taking etoricoxib should refrain from driving or operating machinery.
4.8 Undesirable effects
The following undesirable effects were reported in patients with OA, RA, chronic low back pain or ankylosing spondylitis treated with etoricoxib 30 mg, 60 mg or 90 mg up to the recommended dose for up to 12 weeks:

System Organ Class	Adverse Reactions	Frequency Category
Infections and infestations	alveolar osteitis	Common
	gastroenteritis, upper respiratory infection, urinary tract infection	Uncommon
Blood and lymphatic system disorders	anaemia (primarily associated with gastrointestinal bleeding), leucopenia, thrombocytopenia	Uncommon
Immune system disorders	hypersensitivity	Uncommon
	angioedema/anaphylactic/ anaphylactoid reactions including shock	Rare
Metabolism and nutrition disorders	oedema/fluid retention	Common
	appetite increase or decrease, weight gain	Uncommon
Psychiatric disorders	anxiety, depression, mental acuity decreased, hallucinations	Uncommon
	confusion, restlessness	Rare
Nervous system disorders	dizziness, headache	Common
	dysgeusia, insomnia, paresthesia/hypoesthesia, somnolence	Uncommon
Eye disorders	blurred vision, conjunctivitis	Uncommon
Ear and labyrinth disorders	tinnitus, vertigo	Uncommon
Cardiac disorders	palpitations, arrhythmia	Common
	atrial fibrillation, tachycardia, congestive heart failure, myocardial ischaemic changes, angina pectoris, myocardial infarction*	Uncommon
Vascular disorders	hypertension	Common
	flushing, cerebrovascular accident, transient ischaemic attack, hypertensive crisis*, vasculitis	Uncommon
Respiratory, thoracic and mediastinal disorders	bronchospasm	Common
	cough, dyspnoea, epistaxis	Uncommon
Gastrointestinal disorders	abdominal pain	Very common
	Constipation, flatulence, gastritis, haemorrhoid/anal reflux, diarrhea, dyspepsia/epigastric discomfort, nausea, vomiting, oesophagitis, oral ulcer	Common
	abdominal distention, bowel movement pattern change, dry mouth, gastroduodenal ulcer, peptic ulcers including gastrointestinal perforation and bowel obstruction, irritable bowel syndrome, pancreatitis	Uncommon
Hepatobiliary disorders	ALT increased, AST increased	Common
	hepatitis	Rare
	hepatic failure, jaundice	Rare
Skin and subcutaneous tissue disorders	ecchymosis	Common
	facial oedema, pruritus, rash, erythema, sebborea	Uncommon
	Stevens-Johnson syndrome, toxic epidermal necrolysis, fixed drug eruption	Rare
Musculoskeletal and connective tissue disorders	muscular cramp/spasm, musculoskeletal pain/stiffness	Uncommon
Renal and urinary disorders	proteinuria, serum creatinine increased, renal failure/renal insufficiency	Uncommon
General disorders and administration site conditions	asthenia/fatigue, flulike disease	Common
	chest pain	Uncommon
Investigations	blood urea nitrogen increased, creatine phosphokinase increased, hyperkalaemia, uric acid increased	Uncommon
	blood sodium decreased	Rare

The following serious undesirable effects have been reported in association with the use of NSAIDs and cannot be ruled out for etoricoxib: nephrotoxicity including interstitial nephritis and nephrotic syndrome.
4.9 Overdose
Administration of single doses of etoricoxib up to 500 mg and multiple doses up to 150mg/day for 21 days did not result in significant toxicity. There have been reports of acute overdosage with etoricoxib, although adverse experiences were not reported in the majority of cases. The most frequently observed adverse experiences were consistent with the safety profile for etoricoxib (e.g. gastrointestinal events, renovascular events). In the event of overdose, it is reasonable to employ the usual supportive measures, e.g. remove unabsorbed material from the GI tract, employ clinical monitoring, and institute supportive therapy, if required. Etoricoxib is not dialysable by haemodialysis; it is not known whether etoricoxib is dialysable by peritoneal dialysis.
5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Anti-inflammatory and antirheumatic products, non-steroids, coxibs
ATC Code: M01AH05
Mechanism of Action
Etoricoxib is an oral, selective cyclo-oxygenase-2 (COX-2) inhibitor within the clinical dose range.
Etoricoxib produced dose-dependent inhibition of COX-2 without inhibition of COX-1 at doses up to 150 mg daily. Etoricoxib did not inhibit gastric prostaglandin synthesis and had no effect on platelet function.
Cyclooxygenase is responsible for generation of prostaglandins. Two isoforms, COX-1 and COX-2, have been identified. COX-2 is the isoform of the enzyme that has been shown to be induced by pro-inflammatory stimuli and has been postulated to be primarily responsible for the synthesis of prostanoid mediators of pain, inflammation, and fever. COX-2 is also involved in ovulation, implantation and closure of the ductus arteriosus, regulation of renal function, and central nervous system functions (fever induction, pain perception and cognitive function). It may also play a role in ulcer healing. COX-2 has been identified in tissue around gastric ulcers in man but its relevance to ulcer healing has not been established.
5.2 Pharmacokinetic properties
Absorption
Orally administered etoricoxib is well absorbed. The absolute bioavailability is approximately 100%. Peak plasma concentrations occur in about 1 hour in fasted adults; food delays absorption by about 2 hours, although it has no effect on the extent of absorption.
Distribution
Etoricoxib is approximately 92% bound to human plasma. The volume of distribution at steady state (Vdss) was approximately 120 L in humans. Etoricoxib crosses the placenta in rats and rabbits, and the blood-brain barrier in rats.
Metabolism
Etoricoxib is extensively metabolised with <1% of a dose recovered in urine as the parent drug. The major route of metabolism to form the 6'-hydroxymethyl derivative is catalysed by CYP enzymes. Five metabolites have been identified in man. The principal metabolite is the 6'-carboxylic acid derivative of etoricoxib formed by further oxidation of the 6'-hydroxymethyl derivative. Those principal metabolites either demonstrate no measurable activity or are only weakly active as COX-2 inhibitors. None of these metabolites inhibit COX-1.
Elimination
Etoricoxib is excreted mainly via the urine (70%) and with only 20% of a dose appearing in the faeces. At steady state the half-life of approximately 22 hours.
Characteristics in patients
Elderly patients: Pharmacokinetics in the elderly (65 years of age and older) are similar to those in the young.
Gender: The pharmacokinetics of etoricoxib are similar between men and women.
Hepatic impairment: Patients with mild hepatic dysfunction (Child-Pugh score 5-6) administered etoricoxib 60 mg once daily had a higher mean AUC as compared to healthy subjects given the same regimen. Patients with moderate hepatic dysfunction (Child-Pugh score 7-9) administered etoricoxib 60 mg every other day had similar mean AUC to the healthy subjects given etoricoxib 60 mg once daily; etoricoxib 30 mg once daily has not been studied in this population. There are no clinical or pharmacokinetic data in patients with severe hepatic dysfunction (Child-Pugh score ≥10).
Renal impairment:
The pharmacokinetics of a single dose of etoricoxib 120 mg in patients with moderate to severe renal insufficiency and patients with end-stage renal disease on haemodialysis were not significantly different from those in healthy subjects. Haemodialysis contributed negligibly to elimination (dialysis clearance approximately 50 ml/min).
Paediatric patients:
The pharmacokinetics of etoricoxib in paediatric patients (<12 years old) have not been studied. The pharmacokinetics in adolescents (aged 12 to 17) weighing 40 to 60 kg given etoricoxib 60 mg once daily and adolescents >60 kg given etoricoxib 90 mg once daily were similar to the pharmacokinetics in adults given etoricoxib 90 mg once daily. Safety and effectiveness of etoricoxib in paediatric patients have not been established.
5.3 Preclinical safety data
Not applicable
6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Core: Calcium hydrogen phosphate, croscarmellose sodium, magnesium stearate, microcrystalline cellulose.
Tablet coating: Polyvinyl Alcohol (E1203), Titanium Dioxide (E171), Glycerol Monocaprate (E471), Talc (E553b) and Sodium Laurilsulfate. The 60 mg and 120 mg tablets also contain Indigo Carmine Aluminium Lake (E132) and Yellow Iron Oxide (E172).
6.2 Incompatibilities
Not applicable.
6.3 Shelf-life
4 years.
6.4 Special precautions for storage
Store below 30°C.
6.5 Nature and contents of container
Etoricoxib Tablets 60 mg, 90 mg and 120 mg are available in cartons of 7's, 10's, 28's, 30's and 100's.

Product Registration Holder in Malaysia
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