pharmaniaga®

ETTRIX
Etoricoxib

ETTRIX FILM-COATED TABLET 60 MG

COMPOSITION
Each film-coated tablet contains 60 mg of Etoricoxib

PRODUCT DESCRIPTION
Green coloured, apple shaped, film coated tablets, marked with "60" on one side and plain on other side.

PHARMACODYNAMICS
Pharmacotherapeutic group:

Anti-inflammatory and antirheumatic products, non- steroids, coxibs,

ATC Code: M01 AH05

Mechanism of action

ETTRIX is a nonsteroidal anti-inflammatory drug (NSAID) that exhibits anti-inflammatory, analgesic, and antipyretic activities. ETTRIX is a potent, orally active, highly selective cyclooxygenase-2 (COX-2) inhibitor within and above the clinical dose range. Two isoforms of cyclooxygenase have been identified: cyclooxygenase-1 (COX-1) and cyclooxygenase-2 (COX-2). COX-1 is responsible for prostaglandin-mediated normal physiologic functions such as gastric cytoprotection and platelet aggregation. Inhibition of COX-1 by nonselective NSAIDs has been associated with gastric damage and platelet inhibition. 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 gastro-intestinal (GI) toxicity and without effects on platelet function.

Published pharmacology data shows that, etoricoxib produced dose-dependent inhibition of COX-2 without inhibition of COX-1 at doses up to 150 mg daily.

The influence on gastroprotective COX-1 activity was also assessed in a published clinical study where prostaglandin synthesis was measured in gastric biopsy samples from subjects administered either etoricoxib 120 mg daily, naproxen 500 mg twice daily, or placebo. ETTRIX did not inhibit gastric prostaglandin synthesis as compared to placebo. In contrast, naproxen inhibited gastric prostaglandin synthesis by approximately 80% compared with placebo. These data further support the COX-2 selectivity of etoricoxib.

Platelet Function
Published data shows that multiple doses of etoricoxib up to 150 mg administered daily up to nine days had no effect on bleeding time relative to placebo. There was no inhibition of *ex vivo* arachidonic acid- or collagen-induced platelet aggregation at steady state with doses of etoricoxib up to 150 mg. These findings are consistent with the COX-2 selectivity of etoricoxib.

PHARMACOKINETICS
Absorption
Available data reports that, the onset of action of etoricoxib occurred as early as 24 minutes after dosing.

Orally administered etoricoxib is well absorbed. The mean oral bioavailability is approximately 100%. Following 120 mg once-daily dosing to steady state, the peak plasma concentration (geometric mean Cmax = 3.6 mcg/mL) was observed at approximately 1 hour (Tmax) after administration to fasted adults. The geometric mean AUC0-24hr was 37.8 mcg•hr/mL. The pharmacokinetics of etoricoxib are linear across the clinical dose range.

Published data indicates that a standard meal had no clinically meaningful effect on the extent or rate of absorption of a dose of etoricoxib 120 mg.

Distribution
Etoricoxib is approximately 92% bound to human plasma protein over the range of concentrations of 0.05 to 5 mcg/mL. The volume of distribution at steady state (Vdss) is approximately 120 L in humans. Reported data demonstrates that etoricoxib crosses the placenta in rats and rabbits, and the blood-brain barrier in rats.

Metabolism
Etoricoxib is extensively metabolized with <1% of a dose recovered in urine as the parent drug. The major route of metabolism to form the 6'-hydroxymethyl derivative is catalyzed by cytochrome P450 (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. These principal metabolites either demonstrate no measurable activity or are only weakly active as COX-2 inhibitors. None of these metabolites inhibit COX-1.

Elimination
Published data shows that following administration of a single 25 mg radiolabelled intravenous dose of etoricoxib to healthy subjects, 70% of radioactivity was recovered in urine and 20% in faeces, mostly as metabolites. Less than 2% was recovered as unchanged drug.

Elimination of etoricoxib occurs almost exclusively through metabolism followed by renal excretion. Steady state concentrations of etoricoxib are reached within seven days of once daily administration of 120 mg, with an accumulation ratio of approximately 2, corresponding to an accumulation half-life of approximately 22 hours. The plasma clearance is estimated to be approximately 50 mL/min.

INDICATIONS
ETTRIX 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
- Chronic low back pain (30 mg and 60 mg only)
- 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

RECOMMENDED DOSAGE
ETTRIX is administered orally. ETTRIX maybe taken with or without food. ETTRIX 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.

Chronic low back pain
The recommended dose is 60mg once daily.

Acute Pain
In the following acute painful conditions, ETTRIX 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 of chronic low back pain should not exceed 60 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 ETTRIX 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 ETTRIX is not recommended. No dosage adjustment is necessary for patients with lesser degrees of renal insufficiency (creatinine clearance ≥30 mL/min).

ROUTE OF ADMINISTRATION
Oral.

CONTRAINDICATIONS
ETTRIX is contraindicated in patients with:
- Hypersensitivity to any component of this product.
- Congestive heart failure (NYHA II-IV).
- Established ischemic heart disease, peripheral arterial disease and/or cerebrovascular disease (including patients who have recently undergone coronary artery bypass graft surgery or angioplasty).
- Pregnancy.
- Contraindication for patients who have increased risk of cardiovascular disease (ischeamic heart disease 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.
- Contraindication for Etoricoxib in patients with hypertension (high blood pressure) whose blood pressure is not under control.

WARNINGS AND PRECAUTIONS
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.

Selective COX-2 inhibitors are not a substitute for aspirin for cardiovascular prophylaxis because of their lack of effect on platelets. Because etoricoxib, a member of this class, does not inhibit platelet aggregation, antiplatelet therapies should not be discontinued.

There is a further increase in the risk of gastrointestinal adverse effects (gastrointestinal ulceration or other gastrointestinal complications) for etoricoxib, other selective COX-2 inhibitors and NSAIDs, when taken concomitantly with acetylsalicylic acid (even at low doses). The relative difference in gastrointestinal safety between selective COX-2 inhibitors + acetylsalicylic acid ***vs***. NSAIDs + acetylsalicylic acid has not been adequately evaluated in long-term clinical trials.

In patients with advanced renal disease, treatment with ETTRIX is not recommended. Clinical experience in patients with estimated creatinine clearance of <30 mL/min is very limited. If therapy with ETTRIX must be initiated in such patients, close monitoring of the patient's renal function is advisable.

Long-term administration of NSAIDs has resulted in renal papillary necrosis and other renal injury. Renal prostaglandins may play a compensatory role in the maintenance of renal perfusion. Therefore, under conditions of compromised renal perfusion, administration of ETTRIX 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 pre-existing significantly impaired renal function, uncompensated heart failure, or cirrhosis. Monitoring of renal function in such patients should be considered.

Caution should be used when initiating treatment with ETTRIX in patients with considerable dehydration. It is advisable to rehydrate patients prior to starting therapy with ETTRIX.

As with other drugs known to inhibit prostaglandin synthesis, fluid retention, edema and hypertension have been observed in some patients taking ETTRIX. The possibility of fluid retention, edema or hypertension should be taken into consideration when ETTRIX is used in patients with pre-existing edema, hypertension, or heart failure. All Nonsteroidal Anti-inflammatory Drugs (NSAIDs), including etoricoxib, can be associated with new onset or recurrent congestive heart failure. Etoricoxib may be associated with more frequent and severe hypertension than some other NSAIDs and selective COX-2 inhibitors, particularly at high doses. Therefore, special attention should be paid to blood pressure monitoring during treatment with etoricoxib. If blood pressure rises significantly, alternative treatment should be considered.

Physicians should be aware that individual patients may develop upper gastrointestinal (GI) ulcers/ulcer complications irrespective of treatment. Although the risk of GI toxicity is not eliminated with ETTRIX, the results of the MEDAL Program

demonstrate that in patients treated with etoricoxib, the risk of GI toxicity with etoricoxib 60 mg or 90 mg once daily is significantly less than with diclofenac 150 mg daily. The risk of endoscopically detected upper GI ulcers was lower in patients treated with etoricoxib 120 mg once daily than in patients treated with the non-selective NSAIDs. While the risk of endoscopically detected ulcers was low in patients treated with etoricoxib 120 mg, it was higher than in patients treated with placebo. Upper GI ulcers/ulcer complications have occurred in patients treated with etoricoxib. These events can occur at any time during use and without warning symptoms. 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.

Based on published clinical trial data, elevations of alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST) (approximately three or more times the upper limit of normal) have been reported in approximately 1% of patients treated for up to one year with etoricoxib 30, 60 and 90 mg daily. Data from published clinical trial suggested that the incidence of elevated AST and/or ALT in patients treated with etoricoxib 60 and 90 mg daily was similar to that of patients treated with naproxen 1000 mg daily, but notably less than the incidence in the diclofenac 150 mg daily group. These elevations resolved in patients treated with etoricoxib, with approximately half resolving while patients remained on therapy. In controlled clinical trials of etoricoxib 30 mg daily versus ibuprofen 2400 mg daily or celecoxib 200 mg daily, the incidence of elevations of ALT or AST was similar.

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, ETTRIX should be discontinued.

ETTRIX 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. Since the pathophysiology of these reactions is unknown, physicians should weigh the potential benefits of prescribing ETTRIX versus the potential risks.

When using etoricoxib in the elderly and in patients with renal, hepatic, or cardiac dysfunction, medically appropriate supervision should be maintained. If these patients deteriorate during treatment, appropriate measures should be taken, including discontinuation of therapy.

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 during post-marketing surveillance. These serious events may occur without warning. Patients appear to be at highest risk for these reactions early in the course of therapy: 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.

ETTRIX may mask fever, which is a sign of infection. The physician should be aware of this when using ETTRIX in patients being treated for infection.

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.

DRUG INTERACTION

Warfarin: Published data reported that in patients stabilized on chronic warfarin therapy, the administration of Etoricoxib 120 mg daily was associated with an approximate 13% increase in prothrombin time International Normalized Ratio (INR). Standard monitoring of INR values should be conducted when therapy with ETTRIX is initiated or changed, particularly in the first few days, in patients receiving warfarin or similar agents.

Rifampin: Co-administration of ETTRIX with rifampin, a potent inducer of hepatic metabolism, produced a 65% decrease in etoricoxib plasma area under the curve (AUC). This interaction should be considered when ETTRIX is co-administered with rifampin.

Methotrexate: Two studies investigated the effects of etoricoxib 60, 90 or 120 mg administered once daily for seven days in patients receiving once-weekly methotrexate doses of 7.5 to 20 mg for rheumatoid arthritis. ETTRIX at 60 and 90 mg had no effect on methotrexate plasma concentrations (as measured by AUC) or renal clearance. In one study, etoricoxib 120 mg had no effect on methotrexate plasma concentrations (as measured by AUC) or renal clearance. In the other study, etoricoxib 120 mg increased methotrexate plasma concentrations by 28% (as measured by AUC) and reduced renal clearance of methotrexate by 13%. Monitoring for methotrexate-related toxicity should be considered when ETTRIX at doses greater than 90 mg daily and methotrexate are administered concomitantly.

Diuretics, Angiotensin Converting Enzyme (ACE) Inhibitors and Angiotensin II Antagonists (AIIAs): Reports suggest that NSAIDs including selective COX-2 inhibitors may diminish the antihypertensive effect of diuretics, ACE inhibitors and AIIAs. This interaction should be given consideration in patients taking ETTRIX concomitantly with these products. In some patients with compromised renal function (e.g., elderly patients or patients who are volume-depleted, including those on diuretic therapy) who are being treated with nonsteroidal anti-inflammatory drugs, including selective COX-2 inhibitors, the co-administration of ACE inhibitors or AIIAs may result in a further deterioration of renal function, including possible acute renal failure. These effects are usually reversible. Therefore, the combination should be administered with caution, especially in the elderly.

Lithium: Reports suggest that non-selective NSAIDs and selective COX-2 inhibitors may increase plasma lithium levels. This interaction should be given consideration in patients taking ETTRIX concomitantly with lithium.

Aspirin: ETTRIX can be used concomitantly with low-dose aspirin at doses for cardiovascular prophylaxis. At steady state, etoricoxib 120 mg once daily had no effect on the anti-platelet activity of low-dose aspirin (81 mg once daily). However, concomitant administration of low dose aspirin with ETTRIX increases the rate of GI ulceration or other complications compared to use of ETTRIX alone.

PREGNANCY AND LACTATION

Pregnancy

The use of etoricoxib, as with any drug substance 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 medicinal products inhibiting prostaglandin synthesis, may cause uterine inertia and premature closure of the ductus arteriosus during the last trimester. Cases of fetal renal dysfunction that have resulted in reduction of amniotic fluid volume (oligohydramnios) have been reported in pregnant women treated with NSAIDs at 20 weeks of gestation or later. In some cases, this may result in neonatal renal dysfunction. Such effects may occur shortly after NSAID treatment initiation; oligohydramnios is often reversible after treatment discontinuation. Etoricoxib is contraindicated in pregnancy. If a woman becomes pregnant during treatment, etoricoxib must be discontinued.

Lactation

Etoricoxib is excreted in the milk of lactating rats. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the possible adverse effects of drugs that inhibit prostaglandin synthesis on nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

ELDERLY

Pharmacokinetics in the elderly (65 years of age and older) are similar to those in the young. In clinical studies, a higher incidence of adverse experiences was seen in older patients compared to younger patients; the relative differences between etoricoxib and control groups were similar in the elderly and the young. Greater sensitivity of some older individuals cannot be ruled out.

UNDESIRABLE EFFECTS

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), leukopenia, thrombocytopenia	Uncommon
Immune system disorders	Hypersensitivity‡ ß	Uncommon
	Angioedema/anaphy-lactic /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, paresthaesia/hypaes-thesia, 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, nonspecific ECG 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, heartburn/acid 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 bleeding, 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‡, urticaria‡	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

* Frequency Category: Defined for each Adverse Experience Term by the incidence reported in the clinical trials data base: Very Common (≥1/10), Common (≥1/100 to <1/10), Uncommon (≥1/1000 to <1/100), Rare (≥1/10,000 to <1/1000), Very Rare (<1/10,000).

‡ This adverse reaction was identified through post-marketing surveillance. Its reported frequency has been estimated based upon the highest frequency observed across clinical trial data pooled by indication and approved dose.

† The frequency category of "Rare" was defined per the Summary of Product Characteristics (SmPC) guidance (rev. 2, Sept 2009) on the basis of an estimated upper bound of the 95% confidence interval for 0 events given the number of subjects treated with etoricoxib in the analysis of the Phase III data pooled by dose and indication (n=15,470).

ß Hypersensitivity includes the terms "allergy", "drug allergy", "drug hypersensitivity", "hypersensitivity", "hypersensitivity NOS", "hypersensitivity reaction" and "nonspecific allergy".

§ Based on analyses of long-term placebo and active controlled clinical trials, selective COX-2 inhibitors have been associated with an increased risk of serious thrombotic arterial events, including myocardial infarction and stroke. The absolute risk increase for such events is unlikely to exceed 1% per year based on existing data (uncommon).

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.

OVERDOSE AND TREATMENT

In published data, administration of etoricoxib at single doses up to 500 mg and multiple doses up to 150 mg/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 experience 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 gastrointestinal tract, employ clinical monitoring, and institute supportive therapy, if required.

Etoricoxib is not dialyzable by hemodialysis; it is not known whether etoricoxib is dialyzable by peritoneal dialysis.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

No studies on the effect of etoricoxib on the ability to drive or use machines have been performed. However, patients who experience dizziness, vertigo or somnolence while taking etoricoxib should refrain from driving or operating machinery.

STORAGE CONDITIONS

Store below 30°C.
Protect from light and moisture.

PACK SIZE

10 tablets per ALU/ALU blisters.
In box 100 tablets (10 x 10's).

SHELF LIFE

Product should not be used beyond the expiry date imprinted on the product packaging.

REGISTRATION NO.

MAL24096064AZ

KEEP MEDICINE OUT OF REACH OF CHILDREN
JAUHI UBAT-UBATAN DARI KANAK-KANAK

For further information, please consult your doctor or your pharmacist.

Revision Number: 01
Date of revision: 11 Sep 2025

PRODUCT REGISTRATION HOLDER / MANUFACTURER:

IDAMAN PHARMA MANUFACTURING SDN BHD (200401023395)
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