For PPB use only	
1.17	**Product Information**
1.17.1	**Summary Product Characteristics (SPC)**

1. Name of the medicinal product

Etoricoxib Tablets 60mg

2. Qualitative and quantitative composition

Each film coated tablet contains

Etoricoxib 60mg

S. No.	Wt. / tablet (mg)	Ingredient	Spec	Overages	Std. Qty for 100,000 tablets (in kg)
1.	60.00	Etoricoxib	IHS	Nil	6.000
2.	60.00	Microcrystalline Cellulose pH 102	BP	Nil	6.000
3.	19.00	Lactose	BP	Nil	1.900
4.	4.50	Croscarmellose Sodium	BP	Nil	0.450
5.	2.50	Magnesium Stearate	BP	Nil	0.250
	Coating				
6.	1.90	Hypromellose E15	BP	Nil	0.190
7.	1.00	Purified Talc	BP	Nil	0.100
8.	1.00	Titanium Dioxide	BP	Nil	0.100
9.	0.10	Sunset Yellow	IHS	Nil	0.010
10.	---	*Isopropyl Alcohol	BP	Nil	q.s
11.	---	*Dichloromethane	BP	Nil	q.s

*Represents solvents will not be present in finished product.
BP – British Pharmacopoeia & IHS-In-House Specification.

3. Pharmaceutical form

Tablet: An orange color circular shape biconvexed film coated tablet, plain on both the sides of the tablet.

4. Clinical particulars

4.1 Therapeutic indications

Etoricoxib is indicated in adults and adolescents 16 years of age and older for the symptomatic relief of osteoarthritis (OA), rheumatoid arthritis (RA), ankylosing spondylitis, and the pain and signs of inflammation associated with acute gouty arthritis. Etoricoxib is indicated in adults and adolescents 16 years of age and older for the short-term treatment of moderate pain associated with dental surgery.

4.2 Posology and method of administration

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. For Acute gouty arthritis, the recommended dose is 120 mg once daily or as directed by physician.
Etoricoxib is contraindicated in children and adolescents under 16 years of age.
Method of administration: Oral.

4.3 Contraindications

Hypersensitivity to the active substance or other pyrrolidone derivatives or to any of the excipients listed.

4.4 Special warnings and precautions for use

Caution is advised with treatment of patients most at risk of developing a gastrointestinal complication with NSAIDs; the elderly, patients using any other NSAID or acetylsalicylic acid concomitantly or patients with a prior history of gastrointestinal disease, such as ulceration and GI bleeding. Patients with significant risk factors for cardiovascular events (e.g. hypertension, hyperlipidaemia, diabetes mellitus, smoking) should only be treated with etoricoxib after careful consideration. Etoricoxib may mask fever and other signs of inflammation. Caution should be exercised when co-administering etoricoxib with warfarin or other oral anticoagulants.

4.5 Interaction with other medicinal products and other forms of interaction

Oral anticoagulants: In subjects stabilised on chronic warfarin therapy, the administration of etoricoxib 120 mg daily was associated with an approximate 13% increase in prothrombin time International Normalised Ratio (INR).
Diuretics, ACE inhibitors and Angiotensin II Antagonists: NSAIDs may reduce the effect of diuretics and other antihypertensive drugs.
Acetylsalicylic Acid: In a study in healthy subjects, at steady state, etoricoxib 120 mg once daily had no effect on the anti-platelet activity of acetylsalicylic acid (81 mg once daily)
Lithium: NSAIDs decrease lithium renal excretion and therefore increase lithium plasma levels

4.6 Fertility, Pregnancy and lactation

Etoricoxib is contraindicated in pregnancy. If a woman becomes pregnant during treatment, etoricoxib must be discontinued. Women who use etoricoxib must 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 most frequently reported adverse reactions were dizziness, headache, dysgeusia, insomnia, paresthaesia/hypaesthesia, somnolence, blurred vision, conjunctivitis, cough, dyspnoea and epistaxis.

4.9 Overdose

Administration of single doses of etoricoxib up to 500 mg and multiple doses up to 150 mg/day for 21 days did not result in significant toxicity.
Treatment: 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.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anti-inflammatory and antirheumatic products, nonsteroids, coxibs, ATC code: MO1 AH05
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. It may also play a role in ulcer healing.

5.2 Pharmacokinetic properties

Absorption: Orally administered Etoricoxib is well absorbed. The absolute bioavailability is approximately 100% .
Distribution: Etoricoxib is approximately 92% bound to human plasma protein over the range of concentrations of 0.05 to 5 μg/ml. The volume of distribution at steady state (Vdss) was approximately 1,20l in humans.
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 catalyzed by CYP

enzymes.

Elimination: Elimination of etoricoxib occurs almost exclusively through metabolism followed by renal excretion.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber.

6. Pharmaceutical particulars

6.1 List of excipients

Microcrystalline Cellulose pH 102

Lactose

Croscarmellose Sodium

Magnesium Stearate

Hypromellose E15

Purified Talc

Titanium Dioxide

Sunset Yellow

Isopropyl Alcohol

Dichloromethane

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 Months

6.4 Special precautions for storage

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

6.5 Nature and contents of container

Commercial Presentation: 4's, 10's, 20's, 30's & 100's

1 x 10's (10 tablets are packed in one Alu-Alu blister and 1 such Alu-Alu blister is kept in one carton along with package insert).

6.6 Special precautions for disposal and other handling

Not applicable.

7. Marketing authorisation holder and Manufacturing Site Address

Marketing authorisation holder:

Company name: INNOCIA LIFESCIENCES PVT. LTD.,

Address: Block A, No.12, Balaji Nagar, Ambattur, Chennai-600 053

Country: INDIA.

Manufacturing Site:

ATOZ Pharmaceutials Pvt.Ltd.,

No.12, Balaji Nagar, Ambattur, Chennai-600053,

India.

8. Marketing authorisation number(s)

Telephone: 044 26585811, 26585855

Telefax: -

E-Mail: ah@innocialife.com

9. Date of first registration / Renewal of the registration

Date of first Authorization: Not Applicable

Date of Latest Renewal: Not Applicable

10. Date of revision of the text: Not Applicable

11. Dosimetry (If Applicable): Not Applicable

12. Instructions for preparation of radiopharmaceuticals (If Applicable): Not Applicable