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

1. Name of the medicinal product

Etoricoxib 90mg and Paracetamol 500mg Tablets

2. Qualitative and quantitative composition

Each film coated tablet contains

Etoricoxib 90mg

Paracetamol BP 500mg

S. No.	Wt. / tablet (mg)	Ingredient	Spec	Overages	Std. Qty for 100,000 tablets (in kg)
1.	90.00	Etoricoxib	IHS	Nil	9.000
2.	500.00	Paracetamol	BP	Nil	50.000
3.	27.34	Maize Starch	BP	Nil	2.734
4.	0.60	Sodium Methyl Hydroxybenzoate	BP	Nil	0.060
5.	0.06	Sodium Methyl Hydroxybenzoate	BP	Nil	0.006
6.	15.00	Maize Starch (for paste)	BP	Nil	1.500
7.	18.00	Povidone K30	BP	Nil	1.800
8.	---	Purified Water	BP	Nil	QS
	Lubrication				
9.	20.00	Croscarmellose Sodium	BP	Nil	2.000
10.	20.00	Purified Talc	BP	Nil	2.000
11.	4.00	Colloidal Anhydrous Silica	BP	Nil	0.400
12.	5.00	Magnesium Stearate	BP	Nil	0.500
	Coating				
13.	14.00	Tab Coat Yellow	IHS	Nil	1.400
14.	---	*Purified Water	BP	Nil	QS

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

3. Pharmaceutical form

Tablet: A yellow color oblong shape biconvexed film coated tablet, Scored in the middle on one side and plain on other side of the tablet.

4. Clinical particulars

4.1 Therapeutic indications

Etoricoxib and Paracetamol Tablet is a pain-relieving medicine. It is used to reduce pain and

inflammation in conditions like rheumatoid arthritis, ankylosing spondylitis, and osteoarthritis. It may also be used to relieve muscle pain, back pain, toothache, or pain in the ear and throat.

4.2 Posology and method of administration

A single dose is recommended or as directed by physician.
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

Etoricoxib and Paracetamol tablet should be used with caution in patients with kidney disease. It is not recommended in patients with severe liver disease and active liver disease.

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.
Cholestyramine: Reduces absorption of paracetamol.
Charcoal: Activated, administered immediately reduces absorption of paracetamol.
Domperidone and metochlopramide: Enhance absorption of paracetamol.

4.6 Fertility, Pregnancy and lactation

Etoricoxib and Paracetamol Tablet may be unsafe to use during pregnancy and lactating.

4.7 Effects on ability to drive and use machines

Etoricoxib and Paracetamol Tablet may decrease alertness, affect your vision or make you feel sleepy and dizzy. Do not drive if these symptoms occur.

4.8 Undesirable effects

Some of the common side effects of this medicine include diarrhea, indigestion, stomach pain, flatulence, swelling of hands and feet, and flu-like symptoms.

4.9 Overdose

Give supportive measures and symptomatic treatment. Drug can be removed from the body by gastric lavage or by inducing emesis. Absorption of the drug can be reduced by administration of activated charcoal.

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. N-acetylcysteine is the specific antidote for Paracetamol poisoning.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Etoricoxib, which is of non-steroidal anti-inflammatory drug (NSAID) class, eases the inflammation and pain by interfering with the cyclooxygenase-2 (COX-2) pathway. Cyclooxygenase-2 enzyme converts arachidonic acid to various inflammatory mediators such as, prostaglandins, interleukins and TNFs. Paracetamol is a potent analgesic and antipyretic. It is also said to inhibit the prostaglandin synthesis in the brain. It exhibits the analgesia by increasing the threshold for pain and antipyresis by acting on the hypothalamic heat regulating centre in the brain.

5.2 Pharmacokinetic properties

Absorption: Orally administered Etoricoxib is well absorbed. The absolute bioavailability is approximately 100%. Paracetamol is rapidly and completely absorbed after oral administration.

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. Paracetamol is distributed mostly in the body in unbound form.

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. Paracetamol is extensively metabolised in the liver.

Elimination: Elimination of Etoricoxib and Paracetamol 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

Maize Starch
Sodium Methyl Hydroxybenzoate
Sodium Propyl Hydroxybenzoate
Povidone K30
Croscarmellose Sodium
Purified Talc
Colloidal Anhydrous Silica
Magnesium Stearate
Tab Coat Yellow
Purified Water

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