

Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:

ETO-WELL P 60 TABLETS

ETO-WELL P 90 TABLETS

2. Qualitative and quantitative composition

ETO-WELL P 60 TABLETS

Each film coated tablet contains :

Etoricoxib 60mg

Paracetamol BP 500mg

ETO-WELL P 90 TABLETS

Each film coated tablet contains :

Etoricoxib 90mg

Paracetamol BP 500mg

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

ETO-WELL P 60 TABLETS

An orange color oblong shape biconvex film coated tablet, Scored in the middle on one side and plain on other side of the tablet.

ETO-WELL P 90 TABLETS

A yellow color oblong shape biconvex 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

ETO-WELL P 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 stabilized 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).

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). NSAIDs decrease lithium renal excretion and therefore increase lithium plasma levels.

Cholestyramine reduces absorption of paracetamol.

Charcoal activated, administered immediately reduces absorption of paracetamol.

4.6 Fertility, pregnancy, and lactation

ETO-WELL P Tablet may be unsafe to use during pregnancy and lactating.

4.7 Effects on ability to drive and use machines.

ETO-WELL P 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.

Healthcare professionals are asked to report any suspected adverse reactions via the PPB website <https://pv.pharmacyboardkenya.org>.

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. 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. 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. 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

| ETOWELL-P 60 | ETOWELL-P 90 |
|-------------------------------|-------------------------------|
| Maize Starch | Maize Starch |
| Sodium Methyl Hydroxybenzoate | Sodium Methyl Hydroxybenzoate |
| Sodium Propyl Hydroxybenzoate | Sodium Propyl Hydroxybenzoate |
| Povidone K30 | Povidone K30 |
| Croscarmellose Sodium | Croscarmellose Sodium |
| Purified Talc | Purified Talc |
| Colloidal Anhydrous Silica | Colloidal Anhydrous Silica |
| Magnesium Stearate | Magnesium Stearate |
| Tab Coat Orange | Tab Coat Yellow |
| Purified Water | 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 authorization holder and manufacturing site addresses**Marketing authorization holder:**

INNOCIA LIFESCIENCES PVT. LTD.,

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

Manufacturing site address:

ATOZ Pharmaceuticals Pvt.Ltd.,

Address: No.12, Balaji Nagar, Ambattur, Chennai-600053, INDIA.

8. Marketing authorization number

ETO-WELL P 60 TABLETS CTD9634

ETO-WELL P 90 TABLETS CTD9631

9. Date of first registration

ETO-WELL P 60: 31/10/2022

ETO-WELL P 90: 31/10/2022

10. Date of revision of the text:

19/09/2023

11. Dosimetry:

Not Applicable

12. Instructions for Preparation of Radiopharmaceuticals:

Not Applicable