Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:

ETO – WELL MR 90mg Etoricoxib 90mg, Paracetamol 500mg and Thiocolchicoside 8mg tablets

2. Qualitative and quantitative composition

Each film-coated tablet contains
Etoricoxib 90mg
Paracetamol BP 500mg
Thiocolchicoside BP 8mg

3. Pharmaceutical form

Tablet: A brown 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 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.

The decision to prescribe a selective COX-2 inhibitor should be based on an assessment of the individual patient's overall risks.

Paracetamol is a mild analgesic and is recommended for the treatment of most painful conditions, for example, headache including migraine, toothache, neuralgia, sore throat, backache, rheumatic pain and dysmenorrhea.

Thiocolchicoside is an adjuvant treatment of painful muscle contractures in acute spinal pathology in adults and adolescents from 16 years onwards.

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 MR 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. The risk or severity of adverse effects can be increased when Acetazolamide is combined with Thiocolchicoside.

4.6 Fertility, pregnancy and Lactation

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

4.7 Effects on ability to drive and use machines

ETO-WELL MR 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.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Pharmacy and Poisons board Pharmacovigilance Electronic Reporting System (PvERS)

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. Thiocolchicoside, is a synthetic sulfur derivative of colchicoside, a naturally occurring glucoside contained in the Colchicum autumnale plant.

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. Oral bioavailability is 25% After intramuscular administration, thiocolchicoside Cmax occur in 30 min and reach values of 113 ng/mL after a 4 mg dose and 175 ng/mL after a 8 mg dose.

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. The apparent volume of distribution of thiocolchicoside is estimated to be approximately 42.7 L after an intramuscular injection of 8 mg.

Metabolism: Etoricoxib is extensively metabolised with <1% of a dose recovered in urine as the parent drug. Paracetamol is extensively metabolised in the liver. Thiocolchicoside is rapidly absorbed after oral administration and metabolized into 3 main metabolites.

Elimination: Elimination of Etoricoxib and Paracetamol occurs almost exclusively through metabolism followed by renal excretion. Thiocolchicoside is not eliminated unchanged, rather as one of three metabolites found in either feces (~79 %) or in urine 20%. 3-demethylcolchicine (M2) and 3-O- glucurono-demethylcolchicine (M1)

are found in both urine and feces, whereas di-demethylcolchicine is found only in feces.

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 Brown
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 Content 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 AluAlu 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

Marketing authorization holder:
INNOCIA LIFESCIENCES PVT. LTD.,
Address: Block A, No.12, Balaji Nagar, Ambattur, Chennai-600 053 INDIA.

Manufacturing site address:
ATOZ Pharmaceutials Pvt.Ltd.,
Address: No.12, Balaji Nagar, Ambattur, Chennai-600053, INDIA.

8. Marketing Authorization Number

CTD9632

9. Date of first authorization/renewal of the authorization

09/08/2023

10. Date of revision of the text

11/05/2025