

## Summary of Product Characteristics for Pharmaceutical Products

### 1. Name of the medicinal product:

ETO-WELL MR 60 TABLETS

### 2. Qualitative and quantitative composition

Each film coated tablet contains :

Etoricoxib 60mg

Paracetamol BP 500mg

Thiocolchicoside BP 8mg

For the full list of excipients, see section 6.1.

### 3. Pharmaceutical form

Tablet: A white 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 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.

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. 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 C<sub>max</sub> 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 White  
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**

CTD9932

**9. Date of first registration**

02/05/2023

**10. Date of revision of the text:**

19/09/2023

**11. Dosimetry:**

Not Applicable

**12. Instructions for Preparation of Radiopharmaceuticals:**

Not Applicable