

NEWCOX-TH

(Etoricoxib 60 mg & Thiocolchicoside 8 mg Tablets)

1.6 PRODUCT INFORMATION

1.6.1 SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

NEWCOX-TH (Etoricoxib 60 mg & Thiocolchicoside 8 mg Tablets)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film coated tablet contains:

Etoricoxib 60 mg

Thiocolchicoside 8 mg

Ferric oxide red & Titanium Dioxide BP

Excipients QS

3. PHARMACEUTICAL FORM

Tablet, Solid dosage form

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

It is used medically to treat orthopedic, traumatological and rheumatologic disorders as well as to treat muscular spasms. It is also used to control the pain and swelling suffered by individuals with four medical conditions:

Rheumatoid Arthritis: Rheumatoid arthritis is a disorder in which joint cartilage becomes inflamed and, over time destroyed.

Gout: Gout is a condition in which uric acid crystals accumulate within the cartilage of joints, resulting in extreme pain and inflammation.

Osteoarthritis: Osteoarthritis concerns the gradual and irreversible degradation of the cartilage located within bone joints.

Ankylosing spondylitis: In this disorder, the joints between the vertebrae in the spinal column come under attack by the immune system, and cause inflammation.

4.2 Posology and method of administration

As directed by the physician

Method of administration

Oral

4.3 Contraindications

Inflammatory bowel disease, Severe congestive heart failure, Active peptic ulceration, Cerebrovascular disease, Lactation Children and adolescent < 16 yr.

4.4 Special warnings and precaution for use

Allergic disorders, coagulation defects; history of cardiac failure, left ventricular dysfunction, hypertension, or in patients with oedema due to other Reasons; elderly, renal, cardiac or hepatic impairment. Withdraw treatment if GI Lesions develop; Caution when Admin to Dehydrated Patients. Regular BP Monitoring is advisable. May mask fever and other signs of infection, pregnancy.

NEWCOX-TH

(Etoricoxib 60 mg & Thiocolchicoside 8 mg Tablets)

4.5 Interaction with other medicinal products and other forms of interaction

This tablet is the combination of Etoricoxib and Thiocolchicoside and has unique dual mode of action i.e in this combination, Etoricoxib used to treat orthopedic and Thiocolchicoside used to control the pain and swelling. Drug interactions occur when it is taken with another drug or with food. Before you take a medication for a particular ailment, you should inform the health expert about intake of any other medications including non-prescription medications, over-the-counter medicines that may increase the effect of Etoricoxib and Thiocolchicoside, so the doctor can warn you of any possible drug interactions.

CYP3A4 Inhibitors or Inducers; Rifampicin, Ethinyloestradiol; Oral Salbutamol and Minoxidil. Antidepressant SSRIs and Venlafaxine may increase risk of bleeding. Risk of side effects increased with concomitant use of Aspirin, Ciclosporin, Ketorolac or other NSAIDs. Lithium and Methotrexate, Coumarins, Phenindione, Phenytoin and Sulphonylureas.

4.6 Pregnancy and Lactation

Plain etoricoxib can be used during pregnancy but this combination is contraindicated during Pregnancy & Lactation.

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

Side effects of Etoricoxib and Thiocolchicoside are most likely to be minor. Like Constipation, diarrhea, dizziness.

If you suffer from serious side effects, then concern your doctor as soon as possible.

4.9 Overdose

Give symptomatic and supportive treatment. Induce gastric emesis and administer activated charcoal to reduce further adsorption of drugs.

5. PHARMACOLOGICAL PROPERTIES

This is the combination of NSAID & muscle relaxant where Etoricoxib plays the role of a non-steroidal anti-inflammatory drug with analgesic, antipyretic & antiarthritic action & Thiocolchicoside plays a major role in relaxing the muscles.

5.1 Pharmacodynamic properties

Mechanism of action

After combination of Etoricoxib and Thiocolchicoside we observed that Etoricoxib is selective inhibitor of COX-2 that decreases GI toxicity and is without effects on platelet function. Thiocolchicoside, is a muscle relaxant, which has been claimed to possess GABA (gamma-Aminobutyric acid) mimetic and glycinergic actions. It is used in the symptomatic treatment of painful muscle spasm.

It has been demonstrated by recent studies concomitant administration of an Etoricoxib and Thiocolchicoside shows significantly better symptoms relief compared with the modest improvement of inflammation with each of the treatment alone.

5.2 Pharmacokinetic properties

Etoricoxib selectively inhibits cyclooxygenase 2 (COX-2).

Bioavailability: 100%

Protein Binding: 92%

NEWCOX-TH

(Etoricoxib 60 mg & Thiocolchicoside 8 mg Tablets)

Metabolism: Hepatic, CYP extensively involved (mainly CYP3A4)

Half-life: 22 hours

Excretion: Renal (70%) and fecal (20%)

5.3 Preclinical safety data

In preclinical studies, etoricoxib has been demonstrated not to be genotoxic.

Etoricoxib was not carcinogenic in mice.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Microcrystalline Cellulose BP

Crospovidone BP

Low substituted Hydroxy propyl cellulose LH11

Sodium Lauryl Sulphate BP

Microcrystalline Cellulose BP Ph 102

Croscarmellose Sodium BP

Colloidal Silicon Dioxide BP

Magnesium Stearate Instacoat Red A05D00934 IH

Instaglow IH

Isopropyl Alcohol BP

Methylene chloride BP

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 30⁰ C. Protect from light and moisture.

Keep Medicine Out of Reach of Children

6.5 Nature and contents of container

3 Blisters of 10 tablets each are packed in carton along with Product insert. (3×10's Alu-Alu Blisters pack)

7. MARKETING AUTHORISATION HOLDER

Star Biotech Limited

Address: 1st floor, Prestige House, Rwandex, Kigali-Rwanda

Telephone: (+250) 785377688 / (+250) 787229914

Email: shantilal.bhanderi@yahoo.com

8. MARKETING AUTHORISATION NUMBER

Not Applicable

9. DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Not Applicable