Summary Product Characteristics (SPC)

1. **Name of the medicinal product:**

   NEWCOX- TH Film-coated Tablet (Etoricoxib 90 mg & Thiocolchicoside 8 mg)

2. **Quality and Quantitative Composition:**

   Each film-coated tablet contains:

   Etoricoxib (In-house).....60 mg

   Thiocolchicoside (In-house).....8 mg

   For the full list of excipients, see section 6.

3. **Pharmaceutical Dosage Form:**

   Film-coated tablet

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 Posology

Posology:

One tablet once or twice daily depending upon severity, as directed by the physician

Method of administration

Etoricoxib + Thiocolchicoside tablet is administered orally.

4.3 Contraindications

Inflammatory bowel disease, Severe congestive heart failure, Active peptic ulceration, Cerebrovascular disease, CrCL<30 mL/min, lactation, children and adolescents < 16

4.4 Special Warnings and precautions 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 administering to dehydrated patients. Regular BP monitoring is advisable. May mask fever and other signs of infection. pregnancy.

4.5 Interaction with other medicinal products and other forms of interaction

This tablet is a combination of etoricoxib and thiocolchicoside and has a unique dual mode of action, i.e., in this combination, etoricoxib is used to treat orthopedic conditions, and thiocolchicoside is used to control 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 and 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, ethinylestradiol; 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 machine:

Patients who experience dizziness, vertigo, or somnolence while taking etoricoxib should refrain from driving or operating machinery.

4.8 Undesirable Effects

Gastrointestinal disorders, including constipation and diarrhea; ischemic cardiac events; hypersensitivity reactions, headache, dizziness, nervousness, depression, drowsiness, insomnia, vertigo, tinnitus, photosensitivity; blood disorders, fluid retention, hypertension; dry mouth, taste disturbance, mouth ulcers; appetite and weight changes; chest pain, fatigue, paresthesia, influenza-like syndrome, myalgia.

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

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 the National Regulatory Authority pharmacovigilance reporting channels.

4.9 Overdose

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

5.0 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.

Pharmacotherapeutic group: NSAID and Muscle relaxant

ATC code: Etoricoxib: M01AH05

Thiocolchicoside: M03BX05

5.1 Pharmacodynamic Properties

Mechanism of action

After the combination of Etoricoxib and Thiocolchicoside, we observed that Etoricoxib is a 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.

Etoricoxib

Like any other COX-2 selective inhibitor, Etoricoxib selectively inhibits isoform 2 of the cyclooxygenase enzyme (COX-2). This reduces prostaglandins (PGs) generation from arachidonic acid.

Thiocolchicoside

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

Thiocolchicoside has a selective and potent affinity for GABA-A receptors and acts on muscular contractures by activating the GABA inhibitory pathways, thereby behaving as a potent muscle relaxant. GABA is the main inhibitory neurotransmitter in the human cortex. GABAergic neurons are involved in myorelaxation, anxiolytic treatment, sedation, and anesthetics. GABA can also modulate heart rate and blood pressure. It also has an affinity for the inhibitory glycine receptors; therefore, it acts as a muscle relaxant. Glycine is an inhibitory neurotransmitter and acts as an allosteric regulator of NMDA (N-methyl-D-aspartate) receptors. It is involved in the processing of motor and sensory data, thereby regulating movement, vision, and audition.

It has been demonstrated by recent studies that concomitant administration of etoricoxib and Thiocolchicoside shows significantly better symptom relief compared with the modest improvement of inflammation with each of the treatments alone.

5.2 Pharmacokinetic Properties

Etoricoxib *selectively inhibits cyclo-oxygenase 2 (COX-2)*

Bioavailability: *100%*

Protein binding: *92%*

Metabolism: *Hepatic, CYP extensively involved (mainly CYP3A4).*

Half-life: *22 hours*

Excretion: *Renal: 70% and Faecal: 20%*

5.3 Preclinical safety data

In preclinical studies, etoricoxib has been demonstrated not to be genotoxic. Etoricoxib was not carcinogenic in mice.

6.0 Pharmaceutical Particulars

6.1 List of Excipients

- Microcrystalline Cellulose BP
- Crospovidone BP
- Low substituted Hydroxypropyl cellulose LH11
- Purified Water
- 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 in a cool, dry place below 30°C.

Keep medicines out of reach of children.

6.5 Nature and Contents of container

3 X 10 tablets are packed in a carton along with the product insert.

7.0 Marketing Authorization Holder

Marketing Authorization Holder:

GALAXY PHARMACEUTICAL LTD.

P.O. BOX 39107-00623, Nairobi, Kenya.

Manufacturer:

SKYBIOTECH LIFE SCIENCES PVT. LTD.

Gut No. 5, Gevrai Tanda, Paithan Road, Aurangabad (M.S), India.

Telephone: (91) (240) 2694545

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Email: aher.sr@yahoo.com

8.0 Marketing authorization number(s)

H2021/CTD8348/15982

9.0 Date of first authorization/renewal of the authorization

Date of first authorization: 20/09/2021

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

20/09/2021