1.6 PRODUCT INFORMATION

1.6.1 SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT
NEWCOX-P (Etoricoxib 60 mg & Paracetamol 325 mg Tablets)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each film coated tablet contains:
Etoricoxib 60 mg
Paracetamol BP 325 mg
Ferric oxide red & Titanium Dioxide BP
Excipients QS

3. PHARMACEUTICAL FORM
Tablet, Solid dosage form

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
• Moderate pain like toothache, nerve pain, headache, muscular pain and back pain.
• Fever
• Common cold and flu
• Gouty arthritis
• Osteoarthritis
• Rheumatoid arthritis
• Ankylosing Spondylitis

4.2 Posology and method of administration
As directed by the physician
Method of administration
Oral

4.3 Contraindications
NEWCOX-P is contraindicated in patients with hypersensitivity towards Etoricoxib and Paracetamol. This drug is also contraindicated in patients with peptic ulcers, hepatic impairment, congestive heart failure and renal impairment.

4.4 Special warnings and precaution for use
Before using Newcox P Tablet, inform your doctor about your current list of medications, over the counter products (e.g. vitamins, herbal supplements, etc.), allergies, pre-existing diseases, and current health conditions (e.g. pregnancy, upcoming surgery, etc.). Some health conditions may make you more susceptible to the side effects of the drug. Take as directed by your doctor or follow the direction printed on the product insert. Dosage is based on your condition. Tell your doctor if your condition persists or worsens. Important counseling points are listed below.
Above 65 years of age
Avoid driving or operating heavy machinery
Avoid smoking
Avoid using it if allergic to Paracetamol

Consult a doctor if you have allergic reactions
Consult a doctor if you have an allergic disorders, coagulation defects, left ventricular dysfunction or hypertension
Do not take for longer than what doctor instructed
Do not take Paracetamol if you consume alcoholic beverages every day
May cause ulcers or bleeding
May increase risk of heart attack and stroke

4.5 Interaction with other medicinal products and other forms of interaction
BEFORE TAKING THIS MEDICINE TELL THE DOCTOR ABOUT ANY MEDICAL PROBLEMS AN ALLERGIES THAT CHILD HAS NOW OR HAS HAD.

Usually 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 in this combination of etoricoxib and Paracetamol Risk of side effects increased with concomitant use of aspirin, ciclosporin & may interact with the following drugs and products.
• Acenocoumarol
• Alcohol
• Anisindione
• Dicumarol
• Ethinyl estradiol
• Interfere with certain laboratory tests
• Juxtapid mipomersen
• Ketoconazole
• Leflunomide
• Lithium

4.6 Pregnancy and Lactation
There are no sufficient and well-controlled studies when it comes to Etoricoxib and Paracetamol administration in pregnant women and nursing mothers. Therefore, if you are pregnant or nursing, discuss with your doctor about your condition before taking this medicine. There are no sufficient and well-controlled studies when it comes to Etoricoxib and Paracetamol administration in pregnant women and nursing mothers.
Therefore, if you are pregnant or nursing, discuss with your doctor about your condition before taking this medicine.

4.7 Effects on ability to drive and use machines
Avoid driving or operating heavy machinery

4.8 Undesirable effects
Side effects of Etoricoxib and Paracetamol are most likely to be minor like:
• Constipation
• Swelling of your face, lips, tongue
• Nausea

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

N-acetylcysteine is the specific antidote for Paracetamol poisoning. Dose: 150 mg /kg body weight as IV infusion over 15 minutes followed by same dose over 20 hours.
Maintenance dose: 75 mg / kg orally every 4 - 6 hours for 2 - 3 days. Haemodialysis can be done in emergency conditions.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Etoricoxib is Antiinflammatory medicines NSAID used to treat rheumatoid, arthritis, Gout and osteoarthritis and Paracetamol is also NSAID and it is used to relieve mild to moderate aches and pains associated with conditions such as headaches, migraine, toothache, teething, colds and flu. It is also useful for reducing fever.
It has been demonstrated by recent studies concomitant administration of Etoricoxib and Paracetamol shows better symptoms relief compared with modest improvement of mild to moderate pain, inflammation and fever.

Mechanism of action
Paracetamol works as a painkiller by affecting chemicals in the body called prostaglandins. Prostaglandins are substances released in response to illness or injury.
Paracetamol blocks the production of prostaglandins, making the body less aware of the pain or injury. Paracetamol reduces temperature by acting on the area of the brain that is responsible for controlling temperature. Etoricoxib selectively inhibits isoform 2 of cyclo-oxigenase enzyme (COX-2). This reduces prostaglandins (PGs) generation from arachidonic acid.

5.2 Pharmacokinetic properties
It is readily absorbed from the gastrointestinal tract with peak plasma concentrations occurring about 10 to 60 minutes after oral administration. It is distributed into most body tissues. Plasma protein binding is negligible at usual therapeutic doses but increases with increasing doses. The elimination half-life varies from about 1 to 3 hours.
It is metabolised extensively in the liver and excreted in the urine mainly as inactive glucuronide and sulfate conjugates.
Etoricoxib selectively inhibits isoform 2 of cyclo-oxigenase enzyme (COX-2).

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
- Croscarmellose Sodium BP
- Maize Starch BP
- PVP K30 BP
- Sodium Lauryl Sulfate BP
- Purified Talc BP
- Magnesium Stearate BP
- Colloidal Silicon Dioxide BP
- Instacoat A05D00934
- Instglow 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 30^0 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

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8. MARKETING AUTHORISATION NUMBER
Not Applicable

9. DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION
Not Applicable