Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:

Torax 10 Tablet

2. Qualitative and quantitative composition

Each film-coated tablet contains Ketorolac Tromethamine USP, 10 mg

Excipient of known effects: Lactose

For the full list of excipients, see section 6.1

3. Pharmaceutical form

Tablet; A white shallow round shaped film coated tablet having break line on one side and engraved "SPL" on other side. Free from any visible defects.

4. Clinical particulars

4.1 Therapeutic indications

Torax 10 tablets are indicated for the short-term management of moderate to severe acute post-operative pain.

4.2 Posology and method of administration

Ketorolac tablets are recommended for short-term use only (up to 7 days) and are not recommended for chronic use. 10 mg every 4 to 6 hours as required. Doses exceeding 40 mg per day are not recommended. For patients receiving parenteral Ketorolac tromethamine and who are converted to Ketorolac tromethamine oral tablets, the total combined daily dose should not exceed 90 mg (60 mg for the elderly, renally-impaired patients and patients less than 50 kg) and the oral component should not exceed 40 mg on the day the change of formulation is made. Patients should be converted to oral treatment as soon as possible.

4.3 Contraindications

Ketorolac tromethamine is contraindicated in patients having hypersensitivity to this drug or other NSAIDs and those patients in whom aspirin or other prostaglandin synthesis inhibitors induce allergic reactions. It is also contraindicated in a history of peptic ulcer or gastro-intestinal bleeding, moderate or severe renal impairment (serum creatinine> 160 micromol/l), a history of asthma, children under 16 years of age. Ketorolac tromethamine is contra-indicated as prophylactic analgesia before surgery due to inhibition of platelet aggregation and is contra-indicated intraoperatively because of the increased risk of bleeding. It is also contraindicated during pregnancy, labor, delivery or lactation.

4.4 Special warnings and precautions for use

Not Applicable

4.5 Interaction with other medicinal products and other forms of interaction

Ketorolac tromethamine should not be used with other NSAIDs or in patients receiving aspirin because of the potential for additive side-effects. Care should be taken when administering Ketorolac tromethamine with anti-coagulants since co-administration may cause an enhanced anti-coagulant effect. Ketorolac tromethamine and other non-steroidal anti-inflammatory drugs can reduce the anti-hypertensive effect of beta-blockers and may increase the risk of renal impairment when administered concurrently with ACE inhibitors, particularly in volume depleted patients. Caution is advised when methotrexate is administered concurrently, since some prostaglandin synthesis inhibiting drugs have been reported to reduce the clearance of methotrexate, and thus possibly enhance its toxicity. Probenecid should not be administered concurrently with Ketorolac tromethamine because of increases in ketorolac plasma level and half-life.

4.6 Pregnancy and Lactation

Safety in human pregnancy has not been established. Ketorolac has been detected in human milk at low levels. Ketorolac is therefore contraindicated during pregnancy, labour or delivery, or in mothers who are breast feeding.

4.7 Effects on ability to drive and use machines

Not Available

4.8 Undesirable effects

Commonly occurring side-effects are nausea, vomiting, gastro-intestinal bleeding, melaena, peptic ulcer, pancreatitis, anxiety, drowsiness, dizziness, headache, hallucination, excessive thirst, inability to concentrate, insomnia, malaise, fatigue, pruritus, urticaria, skin photosensitivity, Lyell's syndrome, Stevens Johnson syndrome, flushing, bradycardia, hypertension, palpitations, chest pain, infertility in female, dyspnoea, asthma, pulmonary oedema, fever & pain at injection site.

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via the relevant national regulatory authority pharmacovigilance.

4.9 Overdose

Symptoms following acute NSAID overdoses are usually limited to lethargy, drowsiness, nausea, vomiting and epigastric pain, which are generally reversible with supportive care. Gastrointestinal bleeding can occur. Hypertension, acute renal failure, respiratory depression and coma may occur, but are rare. Anaphylactoid reactions have been reported with therapeutic ingestion of NSAIDs and may occur following an overdose.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anti-inflammatory agents, non-steroids
ATC Code: S01BC05

Torax® is a potent analgesic of the non-steroidal anti-inflammatory drugs (NSAID). It inhibits the cyclo-oxygenase enzyme system and hence prostaglandin synthesis. Thus it gives minimal inflammatory effect at its analgesic effect. Torax® is not an anesthetic agent and possesses no sedative or anxiolytic properties; therefore it is not recommended as a preoperative medication for the support of anesthesia when these effects are required. It is not an opioid and has no known effects on opioid receptors.

5.2 Pharmacokinetic properties

Absorption

Ketorolac tromethamine is 100% absorbed after oral administration. Oral administration of ketorolac tromethamine after a high-fat meal resulted in decreased peak and delayed time-to-peak concentrations of ketorolac tromethamine by about one hour. Antacids did not affect the extent of absorption.

Distribution

The mean apparent volume (Vβ) of ketorolac tromethamine following complete distribution was approximately 13 liters. This parameter was determined from single-dose data. The ketorolac tromethamine racemate has been shown to be highly protein bound (99%). Nevertheless, plasma concentrations as high as 10 mcg/mL will only occupy approximately 5% of the albumin binding sites. Thus, the unbound fraction for each enantiomer will be constant over the therapeutic range. A decrease in serum albumin, however, will result in increased free drug concentrations. Ketorolac tromethamine is excreted in human milk.

Metabolism

Ketorolac tromethamine is largely metabolized in the liver. The metabolic products are hydroxylated and conjugated forms of the parent drug. The products of metabolism, and some unchanged drug, are excreted in the urine.

Excretion

The principal route of elimination of ketorolac and its metabolites is renal. About 92% of a given dose is found in the urine, approximately 40% as metabolites and 60% as unchanged ketorolac. Approximately 6% of a dose is excreted in the feces. A single-dose study with 10 mg ketorolac tromethamine (n = 9) demonstrated that the S-enantiomer is cleared approximately 2 times faster than the R-enantiomer and that the clearance was independent of the route of administration. This means that the ratio of S/R plasma concentrations decreases with time after each dose. There is little or no inversion of the R- to S- form in humans.

The half-life of the ketorolac tromethamine S-enantiomer was approximately 2.5 hours (SD ± 0.4) compared with 5 hours (SD ± 1.7) for the R-enantiomer. In other studies, the half-life for the racemate has been reported to lie within the range of 5 to 6 hours.

5.3 Preclinical safety data

Not Applicable

6. Pharmaceutical Particulars

6.1 List of Excipients

Lactose

Microcrystalline Cellulose (Avicel PH 101)

Sodium Starch Glycolate

Povidone K-30

Magnesium Stearate

Isopropyl Alcohol

Opadry-OY-S- 38921 (White)

6.2 Incompatibilities

Not Applicable

6.3 Shelf-Life

24 months

6.4 Special Precautions for storage

Do not store above 30°C. Protect from light and moisture. Keep out of the reach of children.

6.5 Nature and Content of container

Alu-Alu Blister pack.

6.6 Special precautions for disposal and other handling

No special requirement

7. Marketing Authorization Holder

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8. Marketing Authorization Number

H2022/CTD8286/16238

9. Date of first authorization/renewal of the authorization

2023 September 04

10. Date of revision of the text

2023 September 04