# Ketoflex

Ketorolac Tromethamine

**Ketoflex** contains Ketorolac Tromethamine which is a member of the pyrrolo-pyrrole group of non-steroidal anti-inflammatory drugs (NSAIDs) and exhibits analgesic, anti-inflammatory as well as anti-pyretic activity. It has more pronounced analgesic activity than most NSAIDs.

## Composition

**Ketoflex** Tablet: Each film coated tablet contains Ketorolac Tromethamine USP 10 mg.

## Pharmacodynamics

Ketorolac Tromethamine inhibits the synthesis of prostaglandins and may be considered as a peripherally acting analgesic and thus provides analgesic, anti-inflammatory and anti-pyretic activities.

## Pharmacokinetics

| | |
|---|---|
| Oral absorption | >95% |
| Presystemic metabolism | <10% |
| Plasma half-life | range 4.45-5.6 hrs. mean 5.4 hrs. |
| Plasma protein binding | 99.2% |

The products of metabolism and some unchanged drugs are excreted in the urine.

## Indication

Ketorolac Tromethamine is recommended for the short-term management of moderate to severe pain such as-

- Postoperative pain
- Acute and chronic musculoskeletal pain
- Renal colic
- Cancer pain

## Dosage and Administration

Patients over 16 years: 10 mg every 4-6 hours (elderly every 6-8 hours); maximum 40 mg daily. Maximum duration of treatment 7 days.

Children over 1 year: The recommended oral dosage for the post-operative pain is 0.25 mg/kg to a maximum of 1 mg/kg/day, with a maximum duration of 7 days. Older children may require somewhat lower dosages, while infants and young children may require slightly higher dosages to achieve the same level of pain relief.

Children under 1 year: Not recommended.

## Use in Pregnancy and Lactation

It is detected in human milk. Safety in pregnancy has not been established. It is not recommended during pregnancy, labour or delivery, and in mothers who are breast - feeding.

## Contraindication

Known hypersensitivity to the drug. Asthma, previous allergic symptoms with aspirin or NSAIDs, active peptic ulceration, severe established renal impairment, prerenal conditions including renal artery stenosis, hypovolaemia or dehydration, congestive heart failure, hypertension, concurrent high-dose therapy with methotrexate, pregnancy, disorders of coagulation or platelet function, concurrent treatment with lithium salts.

## Side Effect

*Gastro-intestinal* - nausea, dyspepsia, abdominal discomfort, gastritis, diarrhoea, constipation, melaena, peptic ulcer, rectal bleeding, stomatitis, vomiting, haemorrhage, perforation pancreatitis.

*Central nervous/musculoskeletal systems* - drowsiness, dizziness, headache, sweating, dry mouth, paraesthesia, convulsions, excessive thirst, insomnia, stimulation, abnormal taste and vision, myalgia, hallucinations, hyperkinesia, hearing loss, tinnitus, aseptic meningitis.

*Renal*- increased urinary frequency, oliguria, acute renal failure, hyponatraemia, hyperkalaemia, haemolytic uraemic syndrome, flank pain (with or without haematuria), raised serum urea, creatinine and urinary symptoms & acute renal failure.

*Cardiovascular/haematological* - flushing, bradycardia, pallor, purpura, thrombocytopenia, hypertension, inhibition of platelet aggregation, postoperative wound haemorrhage and haematoma.

*Respiratory* - dyspnoea, asthma, pulmonary oedema.

*Dermatological* - pruritus, urticaria, lyell's syndrome, stevens - Johnson syndrome, exfoliative dermatitis, maculopapular rash.

*Hypersensitivity reactions*-anaphylaxis, bronchospasm, laryngeal oedema, hypotension, flushing and rash. Such reactions may occur in patients with or without known sensitivity to ketorolac or other NSAIDs.

*Other*- asthenia, oedema, weight gain, abnormalities of liver function tests.

## Precaution

Precaution should be taken in the following conditions

- Elderly
- Allergic disorder
- Renal, cardiac & hepatic impairment
- Porphyria
- Patient with low body weight (<50kg).

## Drug Interaction

Potentially hazardous interactions occur with methotrexate, diuretics, lithium, warfarin. Ketorolac should not be used in conjunction with other NSAIDs. Probenecid reduces renal excretion of ketorolac and lower doses are required. Digoxin is highly protein bound but is not significantly displaced by ketorolac.

## Storage

Keep in a cool dry place, away from light. Keep out of the reach of children.

## Packaging

**Ketoflex** tablet : Each box contains 2x10 / 3x10 tablets in blister pack.

Manufactured by
**SOMATEC PHARMACEUTICALS LTD.**
SARULIA, DEMRA, DHAKA, BANGLADESH