Kop®

Ketoprofen BP

COMPOSITION

Kop® 2.5% Gel : Each 100 gm gel contains 2.50 gm Ketoprofen BP.

PHARMACOLOGY

Ketoprofen (**Kop**®) is a non-steroidal anti-inflammatory drug (NSAID) with analgesic and antipyretic actions. In addition to the inhibition of prostaglandin synthesis, it stabilizes lysosomal membranes in vitro and in vivo, inhibits leukotriene synthesis in vitro at high concentrations, and also exhibits antibradykinin activity in vivo. Ketoprofen (**Kop**®) produces analgesia by inhibiting the synthesis of prostaglandins peripherally and centrally. It has also been suggested that Ketoprofen (**Kop**®) causes the suppression of prostaglandin synthesis in the CNS (probably in the hypothalamus) leading to its antipyretic effect. Ketoprofen (**Kop**®) is rapidly and almost completely absorbed from the GI tract. It is approximately 99% bound to plasma protein, mainly albumin. Following single or multiple oral doses in healthy adults, the elimination half-life of the drug has averaged 1.1-4 hours. It is rapidly and extensively metabolized in the liver, principally via conjugation with glucuronic acid. Following a single oral dose of Ketoprofen in healthy adults, about 50-90% of the drug is excreted in urine and about 1-8% in faeces within 1-5 days; most urinary excretion occurs within 12-24 hours and most faecal excretion occurs within 24-48 hours. In case of IM injection, peak concentration of approximately 10 mg/L is reached at about 0.5-0.75 hour after a 100 mg dose. The elimination half-life is approximately 1.88 hour.

INDICATION

Kop® 2.5% Gel is an anti-inflammatory and analgesic preparation to be applied topically to the painful area. It is indicated as a short-term treatment for traumatic lesions (sprains, tendinitis, edema, bruises) and pain.

DOSAGE AND ADMINISTRATION

Kop® 2.5% Gel: **Kop**® 2.5% Gel is to be applied to the painful area twice daily.

ADVERSE EFFECT

Adverse reactions to Ketoprofen are usually mild and mainly involve the GI tract, particularly upper GI tract. Most Ketoprofen-induced adverse effects occur during the first month of treatment, and the frequency of adverse effects generally decreases with continued therapy.

Adverse reactions involving digestive system are dyspepsia, nausea, abdominal pain, diarrhoea, constipation, flatulence, anorexia, vomiting, stomatitis and that involving nervous system are headache, dizziness, malaise, depression, nervousness, dreams, etc. Other reactions are tinnitus, visual disturbance, rash, impairment of renal function, signs or symptoms of urinary-tract irritation.

CONTRAINDICATION AND PRECAUTION

Ketoprofen is contraindicated in patients with known hypersensitivity to the drug. Ketoprofen is contraindicated in patients in whom asthma, urticaria, or other sensitivity reaction is precipitated by aspirins or other NSAIDs, since severe, rarely fatal, anaphylactic reactions to Ketoprofen have been reported in these patients.

The risk of potentially serious adverse GI effects should be considered in patients receiving Ketoprofen, particularly in patients receiving chronic therapy with the drug. Ketoprofen should be used in patients with GI bleeding or active peptic ulceration only when the potential benefits justify the possible risks.

Ketoprofen should be used with caution in patients who may be adversely affected by a prolongation of bleeding time (e.g. patients receiving anticoagulant therapy), since the drug may inhibit platelet function. Ketoprofen should be used with caution in patients with heart failure, hypertension, or other conditions associated with fluid retention, since peripheral edema has been observed in some patients receiving the drug.

Liver function should be monitored periodically during long-term Ketoprofen therapy. Ketoprofen injection must not be given intravenously. Ketoprofen gel should not be applied to patients who have allergy to ketoprofen, other anti-inflammatory agents and aspirin.

DRUG INTERACTION

As Ketoprofen may cause GI bleeding, inhibit platelet aggregation and prolong bleeding time, the drug should be used with caution and the patient should be carefully observed if the drug is used concomitantly with any anticoagulant or thrombolytic agent. Concomitant administration of Ketoprofen and hydrochlorothiazide has resulted in decreased urinary excretion of potassium and chloride compared with hydrochlorothiazide alone. Ketoprofen and salicylates appear to interact in a complex manner and they should not be used concomitantly. Concomitant use of Ketoprofen and probenecid is also not recommended. Ketoprofen should be avoided in patients receiving methotrexate.

USE IN PREGNANCY AND LACTATION

Embryopathic effects have not been recorded with Ketoprofen, but it is recommended to avoid medication during pregnancy.

Trace amounts of the drug appear in breast milk and it should not be used during breast feeding unless unavoidable.

STORAGE

Kop® 2.5% Gel: Store below 30ºC. Protect from light. Keep out of the children's reach.

HOW SUPPLIED

Kop® 2.5% Gel : Each tube contains 10 / 20 / 30 / 60 gm gel.

SQUARE