Ketro

(Ketorolac Tromethamine)
Sterile Ophthalmic Solution

کیٹرو

کیٹورولیک ٹرومیتھامین

COMPOSITION:
Each ml contains:
Ketorolac Tromethamine .....5mg.
(Vega Specs.)
Preservative: Benzalkonium chloride

CLINICAL PHARMACOLOGY:
Ketorolac tromethamine (Ketro) is a nonsteroidal anti-inflammatory drug which, when administered systemically has demonstrated analgesic, anti-inflammatory and anti-pyretic activity. The mechanism of action is thought to be due in part, to its ability to inhibit prostaglandin biosynthesis. Ketorolac tromethamine (Ketro) given systemically doesn't cause pupil constriction. Two drops of Ketorolac 0.5% ophthalmic solution instilled into eyes of patients 12 hours & 1 hour prior to cataract extraction achieved measurable levels in 8 of 9 patients eyes (mean Ketorolac concentration 95ng/ml aqueous humour, range 40 to 170 ng/ml). Ocular administration of Ketorolac tromethamine (Ketro) reduces prostaglandin E_2 (PGE_2) levels in aqueous humour. The mean concentration of PGE_2 was 80 pg/ml in aqueous humour of eye receiving vehicle & 28 pg/ml in the eyes receiving Ketorolac tromethamine (Ketro) ophthalmic solution. One drop of 0.5% Ketorolac ophthalmic solution was instilled into one eye and one drop of vehicle into the other eye TID in 26 normal subjects. Only 5 of 26 patients had a detected amount of Ketorolac in their plasma (range 10.7 to 22.5 ng/ml) at day 10 during topical ocular treatment. Two controlled clinical studies showed that Ketorolac tromethamine (Ketro) ophthalmic solution was significantly more effective than its vehicle in relieving ocular itching caused by seasonal allergic conjunctivitis.

INDICATIONS AND USAGE:
Ketro (Ketorolac tromethamine) is indicated for the relief from the symtoms of ocular allergy. Also indicated for relief of pain after refractive procedures. & corneal trauma, for prophylaxis and relief of post operative ocular inflammation in patients undergoing cataract extraction with or without implant of intraocular lens, for prophylaxis and treatment of cystoid macular edema and for presentation of intraoperative miosis.

CONTRAINDICATIONS:
Ketro (Ketorolac tromethamine) ophthalmic solution is contraindicated in patients with previously demonstrated hypersensitivity to any ingredient in the formulation.

WARNINGS:
There is the potential for cross-sensitivity to acetylsalicylic acid, phenylacetic acid derivatives and other non steriodal anti-inflammatory drugs. Therefore caution should be taken when treating individuals who have previously exhibited sensitivities to these drugs. With some NSAID's there exists the potential for increased bleeding time due to interference with thrombocyte aggregation. There have been reports that ocularly applied NSAID's may cause increased bleeding of ocular tissues in conjunction with ocular surgery.

PRECAUTIONS:
General: It is recommended that Ketro ophthalmic solution be used with caution in patients with known bleeding tendencies or who are receiving other medicaton which may prolong bleeding time.
Carcinogenesis, mutagenesis & impairment of fertility: An 18-months study in mice at oral dose of Ketorolac tromethamine (Ketro) equal to the parenteral dose MRHD (maximum recommended human dose) and a 24-months study in rats at oral dose 2.5 times the parenteral MRHD, showed no evidence of tumorigenicity. Ketorolac (Ketro) was not mutagenic in Ames test, unscheduled DNA synthesis and repair and in forward mutation assays. Ketorolac did not cause chromosome breaking in the in vivo mouse micronucleus assay. Impairment of fertility did not occur in male or female rats at oral dose of 9mg/kg and 16mg/kg respectively.
Pregnancy: Pregnancy category C: Reproduction studies have been performed in rabbits, using daily oral doses at 3.6 mg/kg (42.35mg/m2) and in rats at 10 mg/kg (59 mg/m2) during organogenesis. Results of these studies did not reveal evidence of teratogenecity to the fetus. Oral dose of Ketorolac tromethamine at 1.5 mg/kg (8.8mg/m2) which was half of the human oral exposure, administrated after gestation day 17 caused dystocia and higher pup mortality in rats. There are no adequate & well-controlled studies in pregnant women. Ketorolac tromethamine (Ketro) should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
Nonteratogenic effects: Because of the known effects of prostaglandin-inhibiting drug on the fetal cardiovascular system, the use of Ketro ophthalmic solution during late pregnancy should be avoided.
Nursing mothers: Caution should be exercised when Ketro is administered to a nursing mother.
Pediatric use: Safety and efficacy in pediatric patients below the age of 12 years have not been established.

ADVERSE REACTIONS:
In patients with allergic conjunctivitis the most frequent adverse events reported with the use of Ketro ophthalmic solution have been transient stinging and burning on instillation. In all development studies conducted with Ketorolac tromethamine (Ketro) ophthalmic solution other adverse effects occurring 1-3% of the time during treatment include ocular irritation, allergic reactions, superficial ocular infections and superficial keratitis. Other adverse effects reported rarely with the use of Ketro ophthalmic solution include eye dryness, corneal filtrates, corneal ulcer and visual disturbances (Blurry vision).

DOSAGE AND ADMINISTRATION:
The recommended dose is one drop four times a day to the affected eye(s) for relief of ocular itching due to seasonal allergic conjunctivitis.
For the treatment of postoperative inflammation in patients who have undergone cataract extraction, one drop should be applied to the affected eye(s) four times daily beginning 24 hours after cataract surgery and continuing through the first 2 weeks of the postoperative period.

HOW SUPPLIED:
Ketro ophthalmic solution is available in 5ml sterile plastic dropper bottle.

INSTRUCTIONS:
Store below 30°C.
Protect from heat and sunlight.
Keep out of reach of children.
Use the solution within four weeks after first opening the bottle.

خوراک: ڈاکٹر کی ہدایات کی مطابق استعمال کریں۔
ہدایات: دوا کو دھوپ اور گرمی سے بچائیں۔
۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
تمام ادویات بچوں کی پہنچ سے دور رکھیں۔
پہلی دفعہ بوتل کھولنے کے بعد دوا کو چار ہفتوں تک استعمال کیا جا سکتا ہے۔

Manufactured by:
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