# Xidolac® Eye Drops

Ketorolac Tromethamine 0.5%

**Description:** Ketorolac tromethamine is a member of the pyrrolo-pyrrole group of nonsteroidal anti-inflammatory drugs (NSAIDs).

**Indication:** Ketorolac tromethamine is indicated for seasonal allergic conjunctivitis and for pain and inflammation in ocular surgery. It is also indicated for the treatment of postoperative inflammation in patients who have undergone cataract extraction.

**Dosage and Administration:** For the treatment of relief of ocular itching due to seasonal allergic conjunctivitis, one drop (0.25 mg) four times a day. 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. It has been safely administered in conjunction with other ophthalmic medications such as antibiotics, beta blockers, carbonic anhydrase inhibitors, cycloplegics, and mydriatics.

**Side Effects:** Transient stinging and burning on instillation, allergic reactions, corneal edema, iritis, ocular inflammation, ocular irritation, superficial keratitis and superficial ocular infections. Corneal infiltrates, corneal ulcer, eye dryness, headaches, and visual disturbance (blurry vision).

**Contraindications:** Contraindicated in patients with previously demonstrated hypersensitivity to any of the ingredients in the formulation.

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

**Precaution:** All topical nonsteroidal anti-inflammatory drugs (NSAIDs) may slow or delay healing. Topical corticosteroids are also known to slow or delay healing. Concomitant use of topical NSAIDS and topical steroids may increase the potential for healing problems. Use of topical NSAIDs may result in keratitis. In some susceptible patients, continued use of topical NSAIDs may result in epithelial breakdown, corneal thinning, corneal erosion, corneal ulceration or corneal perforation. These events may be sight threatening. Patients with evidence of corneal epithelial breakdown should immediately discontinue use of topical NSAIDs and should be closely monitored for corneal health.

**High Risk Group:** Pregnancy Category C: There is no adequate and well-controlled studies in pregnant women. The drug should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. The use of drug during late pregnancy should be avoided. *Nursing Mothers:* Caution should be exercised when ophthalmic solution is administered to a nursing woman. *Pediatric Use:* Safety and efficacy in pediatric patients below the age of 3 have not been established. *Geriatric Use:* No overall differences in safety or effectiveness have been observed between elderly and younger patients.

**Drug Interactions:** No information available.

**Pharmaceutical Precautions:** Store in a cool and dry place, away from light. Keep out of reach of children.

**Commercial Pack:** Xidolac® 0.5% Eye Drops: Plastic dropper bottle containing 5 ml of sterile solution. Each ml contains Ketorolac Tromethamine USP 5 mg.

# Xidolac® IM/IV Injection

Ketorolac Tromethamine

**Description**

Ketorolac Tromethamine is a drug of pyrrolo-pyrrole group of nonsteroidal anti-inflammatory drug (NSAID). Ketorolac Tromethamine inhibits synthesis of prostaglandin and may be considered as a peripherally acting analgesic. The biological activity of Ketorolac Tromethamine is associated with the S-form. It is highly protein bound and is largely metabolized in liver. The products of metabolism and some unchanged drugs are excreted in the urine.

**Indications**

Ketorolac Tromethamine is indicated for the short-term management of moderate to moderately severe acute pain that requires analgesia at the opioid level (usually in a postoperative setting).

**Dosage and Administration**

Xidolac injection may be used as a single or multiple doses, on a regular or when necessary schedule for the management of moderately severe, acute pain that requires analgesia at the opioid level, usually in a postoperative setting. When administering Xidolac injection, the IV bolus must be given over no less than 15 seconds. The IM administration should be given slowly and deeply into the muscle. The analgesic effect begins within 30 minutes with maximum effect in 1 to 2 hours after dosing IV or IM. Duration of analgesic effect is usually 4 to 6 hours.

*Single-Dose Treatment:* The following regimen should be limited to single administration use only.

*Adult Patients:*

*IM Dosing:*

*Patients <65 years of age:* One dose of 60 mg. Patients >65 years of age, renally impaired and/or less than 50 kg of body weight: One dose of 30 mg.

*IV Dosing:*

*Patients <65 years of age:* One dose of 30 mg. Patients >65 years of age, renally impaired and/or less than 50 kg of body weight: One dose of 15 mg.

*Pediatric Patients (2 to 16 years of age):*

*IM Dosing:* One dose of 1 mg/kg up to a maximum of 30 mg.

*IV Dosing:* One dose of 0.5 mg/kg up to a maximum of 15 mg.

*Multiple-Dose Treatment (IV or IM):*

*Patients <65 years of age:* The recommended dose is 30 mg Xidolac injection every 6 hours. The maximum daily dose should not exceed 120 mg. Patients >65 years of age, renally impaired patients and patients less than 50 kg: The recommended dose is 15 mg Xidolac injection every 6 hours. The maximum daily dose for these populations should not exceed 60 mg. For breakthrough pain, do not increase the dose or the frequency of Ketorolac Tromethamine.

*Conversion from Parenteral to Oral Therapy:*

Xidolac tablets may be used either as monotherapy or as follow-on therapy to parenteral Ketorolac. When Xidolac tablets are used as a follow-on therapy to parenteral Ketorolac, the total combined daily dose of ketorolac (oral + parenteral) should not exceed 120 mg in younger adult patients or 60 mg in elderly patients on the day the change of formulation is made. On subsequent days, oral dosing should not exceed the recommended daily maximum of 40 mg. Xidolac IM should be replaced by Xidolac tablet as soon as feasible. The total duration of combined parenteral and oral treatment should not exceed 5 days.

**Contraindications**

Ketorolac Tromethamine is contraindicated in patients with known hypersensitivity to NSAIDs and any of the components to Ketorolac Tromethamine. Moreover, the drug is contraindicated to patients with the history of asthma, nasal polyp, angioedema, peptic ulcer and bleeding disorders.

**Adverse Effects**

It is generally well tolerated. However, side effects like dry mouth, excessive thirst, psychotic reactions, convulsion, myalgia, hyponatremia, hyperkalemia, raised blood urea and creatinine, renal failure, hypertension, bradycardia, chest pain, purpura, post operative haemorrhage, haematoma, liver function changes etc. may occur.

**Precautions**

Precaution should be taken in the following conditions:

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

**High risk group**

*Pregnancy & Lactation:*

Ketorolac Tromethamine is contraindicated in pregnancy and lactation.

**Drug Interactions**

Warfarin, digoxin, heparin and salicylate should be used carefully with Ketorolac Tromethamine.

**Pharmaceutical Precautions**

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

**Commercial Pack**

Xidolac 10 IM/IV Injection*:* Box containing 1 x 5 ampoules of 1 ml in blister pack. Each 1 ml ampoule contains Ketorolac Tromethamine USP 10 mg.

Xidolac 30 IM/IV Injection: Box containing 1 x 1 ampoule of 1 ml in blister pack. Each 1 ml ampoule contains Ketorolac Tromethamine USP 30 mg.

BEXIMCO PHARMA

Manufactured by

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