KETOROLAC TROMETHAMINE- ketorolac tromethamine solution
Direct Rx

Ketorolac Tromethamine

Before you use Ketorolac Tromethamine Ophthalmic solution 0.5% for the first time:

1.Check to make sure that the tamper evident ring between the bottle and the cap is not broken (See Figure A). If the tamper evident ring is broken or missing, contact your pharmacist.

[Img-fig-a]

2.Tear off the tamper evident ring (See Figure B).

[Img-fig-b]

3.To open the bottle, remove the cap by turning it in the counterclockwise direction (See Figure C).

[Img-fig-c]

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Rev.10/2021

17.1 Slow or Delayed Healing

Patients should be informed of the possibility that slow or delayed healing may occur while using nonsteroidal anti-inflammatory drugs (NSAIDs).

17.2 Avoiding Contamination of the Product

Patients should be instructed to avoid allowing the tip of the bottle to contact the eye or surrounding structures because this could cause the tip to become contaminated by common bacteria known to cause ocular infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions.

Also, to avoid the potential for cross-contamination, the patient should be advised to use one bottle for each eye following bilateral ocular surgery. The use of the same bottle of topical eye drops for both eyes following bilateral ocular surgery is not recommended.

17.3 Contact Lens Wear

Patients should be advised that ketorolac tromethamine ophthalmic solution 0.5% should not be administered while wearing contact lenses.

17.4 Intercurrent Ocular Conditions

Patients should be advised that if they develop an intercurrent ocular condition (e.g., trauma or infection) or have ocular surgery, they should immediately seek their physician’s advice concerning the continued use of ketorolac tromethamine ophthalmic solution 0.5%.

17.5 Concomitant Topical Ocular Therapy

Patients should be advised that if more than one topical ophthalmic medication is being used, the medicines should be administered at least 5 minutes apart.

Manufactured by:

Micro Labs Limited

Bangalore-560099, INDIA.

Manufactured for:

Micro Labs USA Inc.

Somerset, NJ 08873

Rev.10/2021

Ketorolac Tromethamine Ophthalmic solution 0.5% is supplied sterile, in white opaque LDPE bottles with white opaque LDPE Nozzles with HDPE grey caps as follows.

3 mL in 5 mL bottle NDC 42571-137-31

5 mL in 5 mL bottle NDC 42571-137-25

10 mL in 10 mL bottle NDC 42571-137-26

Storage: Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Two controlled clinical studies showed that ketorolac tromethamine ophthalmic solution was significantly more effective than its vehicle in relieving ocular itching caused by seasonal allergic conjunctivitis.

Two controlled clinical studies showed that patients treated for two weeks with ketorolac tromethamine ophthalmic solution were less likely to have measurable signs of inflammation (cell and flare) than patients treated with its vehicle.

Results from clinical studies indicate that ketorolac tromethamine has no significant effect upon intraocular pressure; however, changes in intraocular pressure may occur following cataract surgery.

Ketorolac tromethamine ophthalmic solution 0.5% is a member of the pyrrolo-pyrrole group of nonsteroidal anti-inflammatory drugs (NSAIDs) for ophthalmic use. Its chemical name is (±)-5-Benzoyl-2,3-dihydro-1H pyrrolizine-1-carboxylic acid compound with 2-amino-2-(hydroxymethyl)-1,3-propanediol (1:1) and it has the following structure:

Ketorolac tromethamine ophthalmic solution 0.5% is supplied as a sterile isotonic aqueous 0.5% solution, with a pH of 7.4. Ketorolac tromethamine ophthalmic solution 0.5% is a racemic mixture of R-(+) and S-(-)- ketorolac tromethamine. Ketorolac tromethamine may exist in three crystal forms. All forms are equally soluble in water. The pKa of ketorolac is 3.5. This white to off-white crystalline substance discolors on prolonged exposure to light. The molecular weight of ketorolac tromethamine is 376.41. The osmolality of ketorolac tromethamine ophthalmic solution 0.5% is 290 mOsmol/kg.

Each mL of ketorolac tromethamine ophthalmic solution contains: Active: ketorolac tromethamine 0.5%. Preservative: benzalkonium chloride 0.01%. Inactives: edetate disodium 0.1%; octoxynol 40; water for injection; sodium chloride; hydrochloric acid and/or sodium hydroxide to adjust the pH.

Ketorolac tromethamine ophthalmic solution 0.5% is indicated for the temporary relief of

ocular itching due to seasonal allergic conjunctivitis. Ketorolac tromethamine ophthalmic solution 0.5% is also indicated for the treatment of postoperative inflammation in patients who have undergone cataract extraction.

KETOROLAC TROMETHAMINE

ketorolac tromethamine solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:72189-335(NDC:42571-137)
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
KETOROLAC TROMETHAMINE (UNII: 4EVE5946BQ) (KETOROLAC - UNII:YZI5105V0L)	KETOROLAC TROMETHAMINE	5 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WATER (UNII: 059QF0KO0R)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

OCTOXYNOL-40 (UNII: 9T1C662FKS)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72189-335-05	5 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/07/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA203410	03/07/2022	

Labeler - Direct Rx (079254320)

Registrant - Direct Rx (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
Direct Rx		079254320	relabel(72189-335)

Revised: 3/2022 Direct Rx