SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

1. NAME OF THE MEDICINAL PRODUCT

Ketoflam Ophthalmic Solution 0.5 % W/V

2. QUALITATIVE AND QUANTITIVE COMPOSITION

Ketorolac Tromethamine USP 0.5 % W/V

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Ophthalmic solution- Eye drops

Clear, colorless to pale yellow solution

4.CLINICAL PARTICULARS

4.1 Therapeutic indications

Ketoflam ophthalmic solution is indicated for the temporary relief of ocular itching due to seasonal allergic conjunctivitis. Ketoflam ophthalmic solution is also indicated for the treatment of postoperative inflammation in patients who have undergone cataract extraction.

4.2 Posology and method of administration

The recommended dose of Ketoflam ophthalmic solution is one drop (0.25 mg) four times a day 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 of KETOFLAM ophthalmic solution 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.

Ketoflam ophthalmic solution has been safely administered in conjunction with other ophthalmic medications such as antibiotics, beta blockers, carbonic anhydrase inhibitors, cycloplegics, and mydriatics

4.3 Contraindications

Ketoflam ophthalmic solution is contraindicated in patients with previously demonstrated hypersensitivity to any of the ingredients in the formulation.

4.4 Special warnings and precautions for use

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 (including hyphemas) in conjunction with ocular surgery.

PRECAUTIONS
General

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.

Postmarketing experience with topical NSAIDs suggests that patients with complicated ocular surgeries, corneal denervation, corneal epithelial defects, diabetes mellitus, ocular surface diseases (e.g., dry eye syndrome), rheumatoid arthritis, or repeat ocular surgeries within a short period of time may be at increased risk for corneal adverse events which may become sight threatening. Topical NSAIDs should be used with caution in these patients.

Postmarketing experience with topical NSAIDs also suggests that use more than 24 hours prior to surgery or use beyond 14 days post-surgery may increase patient risk for the occurrence and severity of corneal adverse events.

It is recommended that Ketoflam ophthalmic solution be used with caution in patients with known bleeding tendencies or who are receiving other medications which may prolong bleeding time.

Information for Patients: Ketoflam ophthalmic solution should not be administered while wearing contact lenses.

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant use of topical NSAIDs and topical steroids may increase the potential for healing problems. If it is going to be used together with topical eye drops there must be 5 minutes of break between administrations. It is recommended to use that KETOFLAM with caution in patients with known bleeding tendencies or who are receiving other medications which may prolong bleeding time. Any drug interactions have been reported. KETOFLAM has been safely administered with ophthalmic medications such as antibiotics, beta blockers, carbonic anhydrase inhibitors, cycloplegics and mydriatics.

4.6 Pregnancy and lactation

Teratogenic Effects: Pregnancy Category C. Ketorolac tromethamine, administered during organogenesis, was not teratogenic in rabbits or rats at oral doses up to 109 times and 303 times the maximum recommended human topical ophthalmic dose, respectively, on a mg/kg basis assuming 100% absorption in humans and animals. When administered to rats after Day 17 of gestation at oral doses up to 45 times the maximum recommended human topical ophthalmic dose, respectively, on a mg/kg basis, assuming 100% absorption in humans and animals, ketorolac tromethamine resulted in dystocia and increased pup mortality. There are no adequate and well-controlled studies in pregnant women. Ketoflam ophthalmic solution 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 drugs on the fetal cardiovascular system (closure of the ductus arteriosus), the use of Ketoflam ophthalmic solution during late pregnancy should be avoided.

Nursing Mothers

Caution should be exercised when Ketoflam 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.

4.7 Effects on ability to drive and use machines

No information about effects on the ability to drive and use machines have been reported. However, caution should be exercised. Transient blurring of vision may occur on instillation of eye drops. Do not drive or use hazardous machinery unless vision is clear.

4.8 Undesirable effects

The most frequent adverse events reported with the use of ketorolac tromethamine ophthalmic solutions have been transient stinging and burning on instillation. These events were reported by up to 40% of

patients participating in clinical trials.

Other adverse events occurring approximately 1% - 10% of the time during treatment with ketorolac tromethamine ophthalmic solutions included allergic reactions, corneal edema, iritis, ocular inflammation, ocular irritation, superficial keratitis, and superficial ocular infections.

Other adverse events reported rarely with the use of ketorolac tromethamine ophthalmic solutions included: corneal infiltrates, corneal ulcer, eye dryness, headaches, and visual disturbance (blurry vision).

Clinical Practice: The following events have been identified during postmarketing use of ketorolac tromethamine ophthalmic solution 0.5% in clinical practice. Because they are reported voluntarily from a population of unknown size, estimates of frequency cannot be made. The events, which have been chosen for inclusion due to either their seriousness, frequency of reporting, possible causal connection to topical ketorolac tromethamine ophthalmic solution 0.5%, or a combination of these factors, include corneal erosion, corneal perforation, corneal thinning and epithelial breakdown.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after Authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to the National Regulatory Authority via Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org/

4.9 Overdose
There is no experience of overdose by the ophthalmic route. If accidentally ingested, symptomatic and supportive treatment should be applied and it should be diluted by applying plenty of fluids.

5.Pharmacological properties

5.1 Pharmacodynamic properties
Pharmacotherapeutic group : Ophthalmic, Non-steroidal Anti-inflammatory drugs, ATC code : S01BC05 Ketorolac tromethamine is a non-steroidal anti-inflammatory drug. The mechanism of its action is based on its ability to inhibit prostaglandin biosynthesis.
Ketorolac tromethamine reduce prostaglandin levels in the aqueous humour after topical ophthalmic administration. Ketorolac tromethamine given systemically does not cause pupil constriction.

5.2 Pharmacokinetic properties

One drop (0.05 mL) of 0.5% KETOFLAM 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 subjects had a detectable amount of ketorolac in their plasma (range 10.7 to 22.5 ng/mL) at Day 10 during topical ocular treatment. When ketorolac tromethamine 10 mg is administered systemically every 6 hours, peak plasma levels at steady state are around 960 ng/mL.

Two controlled clinical studies showed that KETOFLAM 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 KETOFLAM 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.

5.3 Preclinical safety data

Acute, sub-acute and chronic studies of KETOFLAM in experimental animals have established the safety of the drug. In addition, octoxinol 40 was separately evaluated for its ocular safety. KETOFLAM was found to be non-irritating, it did not demonstrate a local anaesthetic effect, it 6 / 7 did not influence the healing of experimental corneal wounds in rabbits, it did not enhance the spread of experimental ocular infections and it did not increase the ocular pressure of normal rabbit eyes.

6.Pharmaceutical particulars

6.1 List of excipients

Benzalkonium chloride solution BP
Sterile aqueous vehicle

6.2 Incompatibilities

None known.

6.3 Shelf life

20 months (unopened), 1 month (after first opening).

6.4 Special precautions for storage

Do not store above 30°C. Do not refrigerate or freeze
Keep container tightly closed.
Discard 1 month after first opening. Store in the original package.

6.5 Nature and contents of container

Drop-Tainer - 5ml Low Density Polyethylene Bottles and
Plugs. Polystyrene or Polypropylene cap.

6.6 Special precautions for disposal and other handling

Do not touch dropper tip to any surface as this may contaminate the contents.
If the drop of medication is not retained in the eye upon dosing for any reason, then instill another drop.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESSES

MERCURY LABORATORIES LIMITED

MAH: Krishna Chemists Ltd, 3rd Floor Metrix Hardware, Lusaka Road.

7. MARKETING AUTHORIZATION NUMBER

H2025/CTD11421/15569

9. DATE OF REGISTRATION / RENEWAL OF REGISTRATION

2025 September 17

10. DATE OF REVISION OF THE TEXT

2025 September 17