Summary of Product Characteristics

1. Name of the Medical Product
Diclomycin

2. Qualitative & Quantitative Composition:
Diclofenac sodium BP.....1mg
Gentamicin sulphate BP
Eq. to gentamicin base.....3mg

Excipient of known effect
Benzalkonium chloride BP.....0.01%w/v

For the full list of excipients, see section 6.1.

3. Pharmaceutical Form:
Eye drops, solution.

Visual description
A clear and colourless solution

4. Clinical Particulars
4.1 Therapeutic Indications:
DICLOMYCIN is indicated for,
- The treatment of superficial bacterial infections including conjunctivitis, blepharitis, blepharoconjunctivitis, keratitis, keratoconjunctivitis, episcleritis, dacryocystitis, corneal ulcers and infected eye sockets.
- The prevention of ocular infection if injury makes the eye or adjacent area vulnerable to infections, after removal of foreign bodies, after burns or laceration of the lids or conjunctiva,or after damage from chemical or physical agents
- Pre and post eye surgery

4.2 Posology and Method of administration:
Posology
The usualrecommended dose of DICLOMYCIN Eye Drops is 2 drops into the conjunctivl sac of the affected eye three or four times a day. In the treatment of acute pseudomonal corneal ulcer the usual dose is 1 to 2 drops every 15 minutes in the daytime. This can be supplemented with the ophthalmic ointment at bedtime.

The usual dose of DICLOMYCIN Eye Drops for prophylaxis, such as after removal of a foreign body or following physical or chemical trauma, is 1 to 2 drops three or four times a day until signs of inflammation have subsided.

For prophylaxis before intra-ocular surgery 1 to 2 drops of DICLOMYCIN Eye Drops should be instilled 4 to 5 times, preferably within 8 hours prior to the surgery.

DICLOMYCIN Eye Drops may be administered as part of the routine postoperative daily dressing of the eye, until recovery from post-surgical inflammation is evident.

4.3 Contraindications:

Hypersensitivity to any ingredient of the formulation. 1 As with all ophthalmic preparations containing benzalkonium chloride, patients are advised not to wear soft contact lenses during treatment with DICLOMYCIN.

4.4 Special warnings & precautions for use

Precautions

Patients who are allergic to aspirin or NSAIDs should be prescribed DICLOMYCIN with caution. Use of topical antibiotics occasionally allows overgrowth of non-susceptible microorganisms such as fungi. If this occurs, or if irritation or sensitization to any of the components of this preparation develops, treatment with it should be discontinued.

To avoid possible contamination of the drops or ointment, do not touch the dropper tip.

Safety and effectiveness in children below the age of 6 years have not been established.

DICLOMYCIN is not to be used as eardrops.

4.5 Interactions with other medicinal products and other forms of Interactions

There are no major drug interactions with the use of DICLOMYCIN Eye Drops. It can be concurrently used with cycloplegics, mydriatics, beta-blockers, antibacterials and carbonic anhydrase inhibitors. DICLOMYCIN should be used with caution along with oral anticoagulants.

4.6 Pregnancy and Lactation

The safety of DICLOMYCIN during pregnancy has not been established. It is not known whether components of DICLOMYCIN are secreted in human milk, caution should beexercised when administered to a nursing woman.

4.7 Effects on ability to drive and use machine*:

None

4.8 Undesirable Effects*:

The most frequently reported adverse reactions with DICLOMYCIN include burning sensation, irritation, non-specific conjunctivitis, conjunctival epithelial defects and conjunctival hyperaemia.

Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Reporting System (PvERS) https://pv.pharmacyboardkenya.org.

4.9 Overdose:

None

5. Pharmacological properties:

5.1 Pharmacodynamic Properties:

Diclofenac sodium is one of a series of phenylacetic acid derivatives that has demonstrated anti-inflammatory and analgesic properties in pharmacological studies. It inhibits the enzyme cyclooxygenase, which is essential in the biosynthesis of prostaglandins (PGs). PGs have been shown in many animal models to be mediators of certain kinds of intra-ocular inflammation. In studies performed in animal eyes, PGs have been shown to cause disruption of the blood-aqueous

humor barrier, vasodilation, increased vascular permeability, leukocytosis and increased intra-ocular pressure. Being a non-steroidal anti-inflammatory drug (NSAID), diclofenac is devoid of the side effects of steroids such as reduced immune response, raised intra-ocular pressure and cataract formation. Clinical studies demonstrate it to be equipotent to steroids in treating ocular conditions.
Gentamicin, an aminoglycosideantibiotic, is active against common bacterial pathogens found in eye infections including coagulase-positive and coagulasenegative Staphylococci, Group A beta-hemolytic and non-hemolytic Streptococci and Streptococcus pneumoniae, Ps. aeruginosa, indole-positive and indolenegative Proteus species, E. coli, species of the *Klebsiella-Enterobacter-Serratia* group,*Citrobacter* species, *Salmonella* species and *Shigella* species, *Moraxella* species, *Providencia* species and *Neisseria* species

5.2 Pharmacokinetics Properties*:
In rabbits, peak concentrations of diclofenac could be demonstrated in the cornea and conjunctiva 30 minutes after application. The highest amounts are found in these and in the choroid and retina. Elimination was fast and almost complete after 6 hours.
Topical application of Gentamicin can result in some systemic absorption. Treatment of large areas can result in plasma concentrations of up to 1µ g/ml.
Gentamicin is not readily absorbed from the gastro-intestinal tract < 10% is bound to plasma protein. Following administration and is excreted >90% in the urine by glomerular filtration. The half-life for its elimination in normal patients is 2 to 3 hours, but can be increased in cases of renal insufficiency.
Effective plasma concentration is 4 - 8ug/ml The volume of distribution (VD) is 0.3 1/kg

5.3 Preclinical safety data
None

6. Pharmaceutical particulars:
6.1 List of Excipients:

Sr. No	Ingredients
1.	Benzalkonium Chloride
2.	Hydroxy propyl B-cyclodextrin
3.	Mannitol
4.	Disodium Edetate
5.	Sodium hydroxide
6.	Hydrochloric acid
7.	Water for Injection

6.2 Incompatibilities:
Not applicable

6.3 Shelf life:
3 years.

After first opening: 4 weeks.

6.4 Special Precautions for storage:
Store below 30°C.
Do not freeze. Keep the bottle in the outer carton in order to protect from light.

6.5 Nature and contents of container:
5 ml Plastic bottle

6.6 Special precautions for disposal:
Any unused product or waste material should be disposed of in accordance with local requirements.

7. Marketing Authorization Holder:
KRISHNA CHEMISTS LTD.
P.O. BOX 3328-00506
Nairobi, Kenya

Manufacturing Site Address:
MERCURY LABORATORIES LIMITED
Unit No. 2/13-2/14, Industrial estate,
Gorwa, Vadodara-390016. Gujarat, India

8. Marketing Authorization Numbers:
H2025/CTD12199/15546

9. Date of first registration /renewal of the registration:
2025 July 30

10. Date of revision of text:
20/06/2025