

DICLOGENTA EYE DROPS

COMPOSITION

Each ml of **DICLOGENTA Eye Drops** contains:

Diclofenac sodium	1 mg
Gentamicin sulphate	3 mg

PHARMACOLOGY

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 aminoglycoside antibiotic, is active against common bacterial pathogens found in eye infections including coagulase-positive and coagulase-negative *Staphylococci*, Group A beta-hemolytic and non-hemolytic *Streptococci* and *Streptococcus pneumoniae*, *Ps. aeruginosa*, indole-positive and indole-negative *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.

INDICATIONS

DICLOGENTA 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

CONTRAINDICATIONS

Hypersensitivity to any ingredient of the formulation.

As with all ophthalmic preparations containing benzalkonium chloride, patients are advised not to wear soft contact lenses during treatment with **DICLOGENTA**.

PRECAUTIONS

Patients who are allergic to aspirin or NSAIDs should be prescribed **DICLOGENTA** 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.

DICLOGENTA is not to be used as eardrops.

PREGNANCY & LACTATION

The safety of **DICLOGENTA** during pregnancy has not been established.

It is not known whether components of **DICLOGENTA** are secreted in human milk, caution should be exercised when administered to a nursing woman.

DRUG INTERACTIONS

There are no major drug interactions with the use of **DICLOGENTA Eye Drops**. It can be concurrently used with cycloplegics, mydriatics, beta-blockers, antibacterials and carbonic anhydrase inhibitors.

DICLOGENTA should be used with caution along with oral anticoagulants.

ADVERSE REACTIONS

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

DOSAGE & ADMINISTRATION

The usual recommended dose of **DICLOGENTA Eye Drops** is 2 drops into the conjunctival 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 **DICLOGENTA 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 **DICLOGENTA Eye Drops** should be instilled 4 to 5 times, preferably within 8 hours prior to the surgery.

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

PRESENTATION

DICLOGENTA Eye Drops are available in a 5 ml vial.