



SUMMARY OF PRODUCT CHARACTERISTICS
(SmPC)

DICLOFENAC[®] EYE DROPS
(Diclofenac Sodium 0.1%^W/_V)

1. NAME OF THE MEDICINAL PRODUCTION

Diclofenac Eye drops

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of Diclofenac eye drops contains 1mg of Diclofenac sodium.

3. PHARMACEUTICAL FORM

Eye drop solution presented in single dose units for administration by instillation in the conjunctival sac.

4. Clinical particulars

4.1 Therapeutic indications

- i. Inhibition of preoperative miosis during cataract surgery (Diclofenac has no intrinsic mydriatic properties and does not replace standard mydriatic agents).
- ii. Treatment of post-operative inflammation in cataract surgery.
- iii. Control of ocular pain and discomfort associated with corneal epithelial defects after photo reactive keratectomy (Laser Eye surgery) or accidental trauma.
- iv. Control of inflammation after Argon Laser Trabeculoplasty (ALT).
- v. The relief of the ocular signs and symptoms of Seasonal Allergic Conjunctivitis (SAC).

4.2 Posology and method of administration

Diclofenac eye drop solution is for instillation into the conjunctival sac only. It should never be injected subconjunctivally, nor should it be directly introduced into the anterior chamber of the eye.

Adults:

Prophylaxis of preoperative miosis	Apply 1 drop four times during the 2 hours before surgery
Control of post-operative inflammation	Apply 1 drop 4 times daily for up to 28 days
Control of Post PRK pain and discomfort	Apply 1 drop 2 times in the hour prior to surgery, one drop 2 times five minutes apart immediately after PRK surgery and then post-operatively 1 drop every 2-5 hours while awake for up to 24 hours.
Control of ocular pain associated with corneal epithelial defects after non-penetrating accidental trauma.	Apply one drop 4 times daily for up to 2 days.
Control of post ALT inflammation	Apply one drop 4 times during the 2 hours before ALT, and then one drop 4 times daily for up to 7 days
The relief of the ocular signs and symptoms of Seasonal Allergic Conjunctivitis	Apply one drop 4 times daily for as long as required

Treatment of inflammation and discomfort after strabismus surgery	One drop 4 times daily in the 1 st week, thrice daily in the 2 nd week, twice daily in the 3 rd week and as required in the 4 th week.
Treatment of ocular pain and discomfort after radial keratotomy	Pre-operatively one drop before surgery Post-operatively one drop immediately after surgery and then one drop 4 times daily for up to 2 days

Paediatric use: No specific studies with Diclofenac Eye Drops have been performed in children.

4.3 Contraindications

Patients with known hypersensitivity to any of the ingredients. Like other non-steroidal anti-inflammatory agents, Diclofenac Eye Drops is also contraindicated in patients in whom attacks of asthma, urticaria or acute rhinitis are precipitated by acetylsalicylic acid or by other drugs with prostaglandin synthetase inhibiting activity. Intraocular use during surgical procedure is also contraindicated.

4.4 Warnings & Precautions

In the presence of infection, or if there is a risk of infection, appropriate therapy (e.g antibiotics) should be given concurrently with Diclofenac Eye Drops. Patients with blurred vision should be refrained from driving a vehicle or operating machine.

4.5 Interaction

There is a theoretical possibility that patients receiving other medications which prolong bleeding time, or with known haemostatic defects may experience exacerbation time with Diclofenac Eye Drops. Clinical findings have shown that Diclofenac Eye Drops can, if necessary, be combined with steroid containing eye drops. To prevent the active substance from being washed out when additional ophthalmic medication is used, an interval of at least 5 minutes between each application should be adhered to.

4.6 Pregnancy and lactation

There is no experience concerning the safety of Diclofenac Eye Drops in human pregnancy. Administration during pregnancy and lactation is therefore not recommended except for compelling reasons.

4.7 Effects on ability to drive and use machines

Patients with blurred vision should refrain from driving a vehicle or operating machines

4.8 Undesirable effects

A mild to moderate burning sensation, blurred vision immediately after instillation of the eye drops, hypersensitivity reactions with itching and reddening, photosensitivity, keratitis punctata, corneal epithelial discontinuity rarely occur.

4.9 Overdose

There is practically no risk of adverse effects due to accidental oral ingestion, since the 5ml eye drop solution contains 5mg of Diclofenac Sodium corresponding to about 10% of recommended adult dose (by oral administration). By way of comparison, the maximum oral daily dose for diclofenac sodium recommended in children is 2mg/kg body weight.

5. Pharmacological properties

5.1 Pharmacodynamics properties

Diclofenac sodium is a non-steroidal compound with pronounced anti-inflammatory and analgesic properties; inhibiting of prostaglandin biosynthesis which has been demonstrated experimentally is regarded as having an important bearing on its mechanism of action. Prostaglandin plays a major role in the causation of inflammation and pain. In clinical trials, Diclofenac sodium has been found to inhibit miosis during cataract surgery, to reduce inflammation following surgical interventions and to reduce ocular pain and discomfort associated with corneal epithelial defects after photoreactive keratectomy (laser eye surgery) or accidental trauma.

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.

6.0 Pharmaceutical particulars.

6.1 List of excipients

Sodium chloride
Disodium Edetate
Boric Acid
Sodium Borate
Polysorbate 80
Benzalkonium Chloride 95%
Polyethylene Glycol 400
Water for injection to

6.2 Incompatibilities

None known to date

6.3 Shelf life

36months

6.4 Storage conditions

Store below 30° C. protect from light and moisture. Replace cap immediately after use. Discard after 28 days of opening the bottle.

6.5 Nature and contents of container

Diclofenac Eye Drops is clear colourless 0.1% ^{w/v} sterile solution available in opaque bottle containing 5ml of the drops.

6.6 Special precautions for disposal and other handling

No special requirements

7.0 APPLICANT/MANUFACTURER

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