

PACKAGE INSERT TEMPLATE FOR DICLOFENAC SODIUM EYE DROP

Brand or Product Name

[Product name] Eye Drop 0.1% w/v

Name and Strength of Active Substance(s)

Diclofenac sodium 0.1% w/v

Product Description

*[Visual description of the appearance of the product (eg colour, odour etc) eg :
Clear, colourless, odourless solution, free of visible particular matters]*

Pharmacodynamics

Diclofenac sodium is a non-steroidal anti-inflammatory agent with analgesic properties. It has marked prostaglandin synthesis inhibitory activity and this is thought to have an important bearing on its mechanism of action.

Diclofenac inhibits miosis during cataract surgery and reduces ocular inflammation and pain associated with corneal epithelial defects after some types of surgical intervention. There is no indication that diclofenac has any adverse effects on wound healing.

Pharmacokinetics

In rabbits, peak concentrations of ¹⁴C -labelled diclofenac could be demonstrated in the cornea and conjunctiva 30 minutes after application. Elimination was rapid and almost complete after 6 hours. Penetration of diclofenac into the anterior chamber has been confirmed in humans. No measurable plasma levels of diclofenac could be found after ocular application of diclofenac sodium eye drop 0.1% w/v.

Indication

- Post-operative inflammation in cataract surgery and other surgical interventions.
- Control of ocular pain and discomfort associated with corneal epithelial defects after laser excimer PRK surgery or accidental trauma.
- Post-traumatic inflammation in non-penetrating wounds.
- Inhibition of miosis during cataract surgery.
- Prevention of cystoid macular oedema after cataract extraction with lens implantation.
- Non-infectious inflammatory conditions affecting the anterior region of the eye (e.g. chronic noninfectious conjunctivitis).

Updated August 2011

Recommended Dosage

Diclofenac sodium eye drop 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

Ocular surgery and its complications

Preoperatively, up to 1 drop 5 times during the 3 hours before surgery.

Postoperatively, 1 drop 3 times on the day of surgery, followed by 1 drop 3-5 times daily for as long as required.

Treatment of pain and discomfort, post-traumatic inflammation

One drop 4 to 6 hourly.

When pain is due to a surgical procedure (e.g. refractive surgery), 1 to 2 drops in the hour preceding surgery, 1 to 2 drops within the first 15 minutes after intervention and 1 drop 4 to 6 hourly for 3 days thereafter.

Elderly

There is no indication that dosage needs to be modified for the elderly.

Paediatric use

Limited experience in children aged 2 years and older is available from clinical trials in strabismus surgery. The dispenser remains sterile until the original closure is broken. Patients must be instructed to avoid allowing the tip of the dispensing container to contact the eye or surrounding structures as this may contaminate the solution.

If more than one medication needs to be instilled in the eye, an interval of at least 5 minutes between application of the different medicinal products must be allowed.

Mode of Administration

Topical ophthalmic

Contraindications

- Hypersensitivity to the active substance or to any of the excipients.
- As with other non-steroidal anti-inflammatory agents, diclofenac sodium eye drop is contraindicated in patients in whom attacks of asthma, urticaria or acute rhinitis are precipitated by acetylsalicylic acid or by other drugs with prostaglandin synthesis inhibiting activity. There is the potential for cross sensitivity to acetylsalicylic acid, phenylacetic acid derivatives, and other non-steroidal anti-inflammatory agents. Therefore, caution should be used when treating individuals who have previously experienced sensitivities to these drugs.

Updated August 2011

Warnings and Precautions

[Specific package insert requirement for diclofenac sodium]

PRECAUTION:

Severe cutaneous reactions, including Stevens - Johnson syndrome and toxic epidermal necrolysis (Lyell's syndrome), have been reported with diclofenac sodium. Patients treated with diclofenac sodium should be closely monitored for signs of hypersensitivity reactions. Discontinue diclofenac sodium immediately if rash occurs.

The anti-inflammatory activity of ophthalmic non-steroidal anti-inflammatory agents (NSAIDs) may mask the onset and/or progression of ocular infections. In the presence of an infection or if there is a risk of infection, appropriate therapy should be given concurrently with diclofenac sodium eye drop.

Although there have been no reported adverse events, there is a theoretical possibility that patients receiving other medications which may prolong bleeding time, or with known hemostatic defects may experience exacerbation with diclofenac sodium eye drop.

The ophthalmic solution is not for injection and it should never be injected subconjunctivally, nor should it be directly introduced into the anterior chamber of the eye.

Effects on ability to drive and use machines

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

Interactions with Other Medicaments

No interactions with other drugs have been reported to date. An interval of at least five minutes between the application of the different medicinal products must be allowed.

Statement on Usage During Pregnancy and Lactation

First and second trimester

Pregnancy category B - Animal studies have so far shown no risk to the fetus but no controlled studies in pregnant women are available.

Third trimester

Pregnancy category D – Diclofenac sodium eye drop should not be used, due to possible risk of premature closure of the ductus arteriosus and possible inhibition of contractions.

Updated August 2011

Following oral administration of 50 mg diclofenac in coated tablets (content of 10 diclofenac sodium eye drop bottles) only traces of the active substance were detected in breast milk and in quantities so small that no undesirable effects on the infant are to be expected.

Adverse Effects / Undesirable Effects

[Specific package insert requirement for diclofenac sodium]

Adverse effects:

Dermatological: Occasional - rashes or skin eruptions.

Cases of hair loss, bullous eruptions, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), and photosensitivity reactions have been reported.

The most frequently observed adverse reaction is a transient, mild to moderate burning sensation in the eye. Other less frequently observed reactions are itching, reddening of the eye and blurred vision immediately after instillation of the eye drops. Keratitis punctata or corneal epithelial defects have been observed, usually after frequent application. In patients with risk factors of corneal ulcer and thinning such as during the use of corticosteroids or with concomitant diseases such as infections or rheumatoid arthritis, diclofenac has been associated, in rare cases, with corneal ulcer or thinning which might become sight-threatening. Most patients were treated for a prolonged period of time. In rare cases dyspnoea and exacerbation of asthma have been reported.

Overdose and Treatment

There is no experience of overdose with diclofenac sodium eye drop. However, inadvertent oral ingestion carries practically no risk of adverse effects as a 5 ml bottle contains only 5 mg diclofenac sodium, corresponding to about 3% of the recommended maximum oral daily dose for an adult. The recommended oral dose for diclofenac to children is 2 mg/kg body weight.

Storage Conditions

Finished product - Store below°C

After opening - Store below°C fordays

* If not, please include this statement – For single use only. Discard any unused portion after opening

Dosage Forms and Packaging Available

[Packaging type & pack size eg

5ml white LDPE bottle with HDPE closure X 5s/box]

Name and Address of Manufacturer

[Name & full address of manufacturer]

Updated August 2011

Name and Address of Marketing Authorization Holder
[Name & full address of marketing authorization holder]

Date of Revision of Package Insert
[day/month/year]