Summary of product characteristics

Epifenac
Eye drops

Table of Contents

1. Name of the medicinal product:

Epifenac Eye drops

2. Qualitative and quantitative composition:
Each 1 ml contains: Diclofenac sodium..... 1 mg
For Inactive ingredients see section 6.1

3. Pharmaceutical form:
Eye drops

4. Clinical particulars:
4.1 Therapeutic indications:
- Inhibition of peroperative miosis during cataract surgery (**Epifenac eye drops** has no intrinsic mydriatic properties and does not replace standard mydriatic agents).
- Treatment of post-operative inflammation in cataract surgery.
- Control of ocular pain and discomfort associated with corneal epithelial defects after excimer PRK surgery or accidental non-penetrating trauma.
- Control of inflammation after Argon Laser Trabeculoplasty (ALT).
- The relief of the ocular signs and symptoms of Seasonal Allergic Conjunctivitis (SAC).
- Treatment of inflammation and discomfort after strabismus surgery.
- Treatment of ocular pain and discomfort after radial keratotomy.

4.2 Posology and method of administration:
Epifenac 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 1st week, thrice daily in the 2nd week, twice daily in the 3rd week and as required in the 4th 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:

Epifenac eye drops are not indicated for use in children. Paediatric experience is limited to a few published clinical studies in strabismus surgery.

Following instillation of the eye drops, nasolacrimal occlusion or closing the eyes for 5 minutes may reduce the systemic absorption. This may result in a decrease in systemic side effects and an increase in local activity.

4.3 Contraindications:

Patients with known hypersensitivity to any of the ingredients.

Like other non-steroidal anti-inflammatory agents, **Epifenac** 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 Special warnings and precautions for use:

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 infection, or if there is a risk of infection, appropriate therapy (e.g. antibiotics) should be given concurrently with **Epifenac**.

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 haemostatic defects may experience exacerbation with **Epifenac**.

Caution should be exercised when topical NSAIDs such as diclofenac are used concomitantly with topical steroids.

Following instillation of the eye drops, nasolacrimal occlusion or closing the eyes for 3 minutes may reduce the systemic absorption. This may result in a decrease in systemic side effects and an increase in local activity.

4.5 Interaction with other medicinal products:

Concomitant use of topical NSAIDs such as diclofenac and topical steroids in patients with significant pre-existing corneal inflammation may increase the risk of developing corneal complications, therefore caution should be used.

An interval of at least five minutes between the application of the different medicinal products must be allowed.

4.6 Pregnancy and lactation:

Pregnancy: There are no data on the use of diclofenac eye drops in pregnancy.

1st and 2nd Trimester: Animal studies have so far shown no risk to the foetus but no controlled studies in pregnant women are available.

3rd Trimester: Diclofenac should not be used, due to a possible risk of premature closure of the ductus arteriosus and possible inhibition of contractions.

Lactation: Diclofenac is excreted in breast milk. However, at therapeutic doses of diclofenac no effects on the suckling child are anticipated. Use of ocular diclofenac is not

recommended during breast feeding unless the expected benefits outweigh the possible risks.

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:
The most frequently observed adverse reaction is a transient, mild to moderate eye irritation.
Other less frequently observed reactions are eye pain, eye pruritus, ocular hyperaemia and blurred vision immediately after instillation of the eye drops.
Punctate keratitis or corneal disorders have been observed, usually after frequent application.
In patients with risk factors of corneal disorders 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 ulcerative keratitis, corneal thinning, punctuate keratitis, corneal epithelium defect and corneal oedema, which might become sight-threatening. Most patients were treated for a prolonged period of time.
Allergic conditions have been reported for ocular reactions such as conjunctival hyperaemia, allergic conjunctivitis, eyelid erythema, oedema, and pruritus, and systemic hypersensitivity reactions such as urticaria, rash, eczema, erythema, pruritus, cough and rhinitis.
In rare cases dyspnoea and exacerbation of asthma have been reported.

4.9 Overdose
There is practically no risk of adverse effects due to accidental oral ingestion, since a 5ml bottle of the eye drops contains only 5mg of diclofenac sodium, corresponding to about 3% of the recommended maximum daily adult dose of diclofenac after 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 Pharmacodynamic properties:
Epifenac eye drops contains diclofenac sodium, a non-steroidal compound with pronounced anti-inflammatory and analgesic properties. Inhibition of prostaglandin biosynthesis, which has been demonstrated experimentally, is regarded as having an important bearing on its mechanism of action. Prostaglandins play a major role in the causation of inflammation and pain.
In clinical trials, diclofenac sodium has been found to:
- Inhibit miosis during cataract surgery.
- Reduce inflammation following surgical interventions.
- Reduce ocular pain and discomfort associated with corneal epithelial defects after excimer PRK surgery or accidental non-penetrating trauma.
- Reduce the incidence of angiographic cystoid macular oedema after cataract surgery but clinical significance remains to be established.

- Reduce ocular inflammation and discomfort more effectively than topical steroids after strabismus surgery whilst avoiding steroidal adverse effects such as delayed conjunctival wound healing and raised intraocular pressure.
- Reduce ocular inflammation, pain and discomfort (photophobia, burning/stinging, foreign body sensation, deep headache-like ocular pain and itching) more effectively than placebo eye drops after corneal incisional surgery such as radial keratotomy.
The effective daily dose after ocular application of **Epifenac eye drops** (approximately 0.25 - 0.5 mg diclofenac sodium) corresponds to less than 1% of the daily dose recommended for **Epifenac** in rheumatic indications.

5.2 Pharmacokinetic properties:
Penetration of diclofenac into the anterior chamber has been confirmed in humans. No measurable levels of diclofenac could be found in humans after ocular application of diclofenac sodium eye drops.

6. Pharmaceutical particulars:
6.1 List of Inactive ingredients:
Benzalkonium chloride, boric acid, sodium borate, disodium edetate, cremophor EL, hydroxypropyl β-cyclodextrin, sodium hydroxide or hydrochloric acid and water for injection.

6.2 Incompatibilities:
None known

6.3 Shelf life:
2 years.

6.4 Special precautions for storage:
Store at a temperature not exceeding 30˚C.

6.5 Nature and contents of container:
5ml plastic bottle dropper.

6.6 Special precautions for disposal and other handling:
Any unused medicine or waste material should be disposed of by taking to your local pharmacy.

7. Marketing authorization holder:
EIPICO

8. Date of revision of the text:
March 2021.