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3 October 2017

Nepafenac

Approved indication: cataract surgery

Ilevro (Novartis)

Bottles containing 3 mg/mL eye drops suspension

Australian Medicines Handbook section 11.3.4

Nepafenac is a non-steroidal anti-inflammatory drug indicated for the prevention and treatment of inflammation and pain associated with cataract surgery. After administration, nepafenac penetrates the cornea and is rapidly metabolised to amfenac by hydrolases. Nepafenac and amfenac work by potentially inhibiting COX-1 and COX-2 enzymes.

One drop a day should be administered the day before surgery, on the day of surgery and then for 14 days after surgery. An extra dose should be given 30–120 minutes before surgery.

In a phase 3 trial of over 2000 patients, nepafenac 0.3% eye drops were significantly better than vehicle eye drops at reducing inflammation in patients who had undergone cataract surgery (see Table). After 14 days of post-surgical treatment, inflammation had resolved in 68.4% of patients receiving nepafenac 0.3% compared with 34% receiving vehicle drops.

Resolution of inflammation was defined as a score of zero for aqueous cells and flare, which were detected using slitlamp biomicroscopy. A secondary endpoint was the percentage of patients who were pain-free at day 14. Of those given nepafenac 0.3%, 91% were pain free compared with 49.7% in the corresponding vehicle group.¹

Patients with a history of ocular surgery, inflammatory eye disease or infection, uncontrolled glaucoma or diabetic retinopathy were excluded from the trial. Other anti-inflammatory drugs, except low-dose aspirin, were not allowed during the trial.

The most common reason for patients discontinuing the trial was treatment failure. This occurred in 2.9% of patients receiving nepafenac 0.3% and 32.7% of those receiving the corresponding vehicle eye drops. Overall, 12.4% of patients had an adverse event. The most common events with nepafenac 0.3% were headache (2.7%, 22/817) and increase in intraocular pressure (1%, 8/817).¹ Treatment-emergent events with nepafenac included one case of eye pain and one case of hypersensitivity.

Nepafenac is contraindicated in people who have hypersensitivity (asthma, urticaria, acute rhinitis) to non-steroidal anti-inflammatory drugs including aspirin. Soft contact lenses should not be used with these eye drops as preservative in the solution may be absorbed by the lenses.

Punctate keratitis was reported in 3% of patients with diabetes following prolonged exposure to nepafenac (>2 months). Post-marketing experience suggests that patients with complicated ocular surgeries or repeat surgery in a short time period, corneal denervation, corneal epithelial defects, diabetes, dry eye syndrome or rheumatoid arthritis may be at risk of serious corneal adverse reactions with topical non-steroidal anti-inflammatory drugs.

Patients should be advised to avoid sunlight while using nepafenac eye drops. Concomitant topical steroids with nepafenac should be used with caution as both drugs can delay healing, particularly in those at risk of corneal adverse reactions.

There are no safety data on nepafenac in pregnant women and it is not recommended during pregnancy or lactation. However, as systemic exposure is negligible after eye drops are administered, the risk of toxicity to the fetus or breastfeeding infant is likely to be low.

Table Efficacy of nepafenac eye drops for pain and inflammation after cataract surgery

Parameter*	Daily eye drops [†]			
	nepafenac 0.3%*	vehicle	nepafenac 0.1%*	vehicle
Ocular inflammation % cured [‡]	68.4% (552/807)	34% (67/197)	70% (568/811)	35.6% (73/205)
Ocular pain % cured	91% (734/807)	49.7% (98/197)	90.9% (737/811)	56.1% (115/205)

* Efficacy outcomes were measured at day 14 after surgery in the intent-to-treat population.

[†] One eye drop a day (for nepafenac 0.3%), or one drop three times a day (for nepafenac 0.1%), was given in the conjunctival sac starting the day before surgery and for 14 days after surgery. An extra dose was given 30–120 minutes before surgery.

[‡] A cure was defined as a score of zero for aqueous cells and flare detected using slitlamp biomicroscopy.

Source: Reference 1

Nepafenac 0.3% eye drops were significantly better at resolving inflammation and pain after cataract surgery than vehicle eye drops. As there were no comparative studies, it is unclear if this product will be more effective than other non-steroidal anti-inflammatory eye drops. However, patients may prefer nepafenac as it only needs to be administered once a day whereas diclofenac and ketolorac need to be taken several times a day.

T manufacturer provided the AusPAR

REFERENCE

1. Modi SS, Lehmann RP, Walters TR, Fong R, Christie WC, Roel L, et al. Once-daily nepafenac ophthalmic suspension 0.3% to prevent and treat ocular inflammation and pain after cataract surgery: phase 3 study. *J Cataract Refract Surg* 2014;40:203-11. <http://dx.doi.org/10.1016/j.jcrs.2013.07.042>

The Transparency Score is explained in [New drugs: transparency, Vol 37 No 1, Aust Prescr 2014;37:27.](#)

At the time the comment was prepared, information about this drug was available on the websites of the [Food and Drug Administration](#) in the USA, the [European Medicines Agency](#) and the [Therapeutic Goods Administration](#).

A:

ANSWERS TO SELF-TEST QUESTIONS

- 1 False 2 True
- 3 False 4 True

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