New drugs

Tafluprost

Approved indication: glaucoma, ocular hypertension
Saflutan (Merck Sharp & Dohme)
single-dose eye drops containing 15 microgram/mL
Australian Medicines Handbook section 11.2.2

The topical prostaglandin analogues, bimatoprost, latanoprost and travoprost, are replacing beta blockers as the first-line treatment for reducing intraocular pressure in open-angle glaucoma. They are thought to work by increasing uveoscleral outflow.

Tafluprost is a new prostaglandin analogue. After being instilled in the eye, it is absorbed through the cornea and hydrolysed to the active metabolite – tafluprost acid. Intraocular pressure begins to decrease 2–4 hours later and the maximum effect is reached after 12 hours.

In a phase III trial, once-daily tafluprost was found to be non-inferior to the beta blocker timolol in 643 randomised patients with open-angle glaucoma or ocular hypertension. These patients had an intraocular pressure of 23–26 mmHg in at least one eye at baseline. After 12 weeks, mean intraocular pressures had reduced to 17.4–18.6 mmHg with tafluprost and 17.9–18.5 mmHg with timolol.[1]

In another phase III trial, tafluprost was compared to latanoprost in 533 patients who had intraocular pressures of 22–34 mmHg at baseline. Mean intraocular pressures were decreased by 7.1 mmHg with tafluprost and 7.7 mmHg with latanoprost. These reductions were sustained over the 24 months of treatment.[2]

Tafluprost can be added to timolol as adjunctive treatment. Timolol acts by reducing the production of aqueous humour so these drugs have potentially additive effects on intraocular pressure. In a trial of 185 patients who had uncontrolled disease with timolol alone, tafluprost reduced intraocular pressure more than placebo when added to therapy. After a four-week run-in period with timolol, adding tafluprost for six weeks reduced pressures by a further 5.49–5.82 mmHg compared to placebo which reduced pressures by 3.99–4.15 mmHg.[3]

The adverse effects of tafluprost are similar to other prostaglandin analogues and mainly relate to the eye. The most common adverse event was ocular hyperaemia which affected 14.2% of patients. Other common events (1–10% patients) in the eye included pruritus, pain, irritation, dryness, increased lacrimation, blurred vision and erythema of the eyelid.

Patients should be warned that long-term use of tafluprost can darken pigmentation of the iris, eyelid and eyelashes. This can be permanent and may become more noticeable if drops are only used in one eye. Eyelashes can also become longer and thicker and increase in number. This is usually reversible.

This product does not contain a preservative so adverse effects from this are not a problem. One drop of tafluprost in the conjunctival sac is recommended each evening. If more than one ophthalmic drug is used, they should be given five minutes apart.

Tafluprost, alone or in combination with timolol, lowers intraocular pressure in patients with open-angle glaucoma or ocular hypertension. In a comparative study, it was slightly less effective than latanoprost. It is unclear how tafluprost will compare to the other prostaglandin analogues.

[T] manufacturer provided the AusPAR

REFERENCES *[A]

1. Chabi A, Varma R, Tsai JC, Lupinacci R, Pigeon J, Baranak C, et al. Randomized clinical trial of the efficacy and safety of preservative-free tafluprost and timolol in patients with open-angle glaucoma or ocular hypertension. Am J Ophthalmol 2012;153:1187-96.
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3. Egorov E, Ropo A; Investigators. Adjunctive use of tafluprost with timolol provides additive effects for reduction of intraocular pressure in patients with glaucoma. Eur J Ophthalmol 2009;19:214-22.

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The Transparency score ([T]) is explained in 'New drugs: T-score for transparency', Aust Prescr 2011;34:26–7.

* At the time the comment was prepared, information about this drug was available on the website of the Food and Drug Administration in the USA (www.fda.gov).

[A] At the time the comment was prepared, information about this drug was available on the website of the Therapeutic Goods Administration (www.tga.gov.au/industry/pm-auspar.htm)

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Some of the views expressed in the following notes on newly approved products should be regarded as tentative, as there may be limited published data and little experience in Australia of their safety or efficacy. However, the Editorial Executive Committee believes that comments made in good faith at an early stage may still be of value. As a result of fuller experience, initial comments may need to be modified. The Committee is prepared to do this. Before new drugs are prescribed, the Committee believes it is important that full information is obtained from the manufacturer's approved product information, a drug information centre or some other appropriate source.