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EPAR summary for the public

DuoTrav

travoprost / timolol

This document is a summary of the European public assessment report (EPAR) for DuoTrav. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for DuoTrav.

What is DuoTrav?

DuoTrav is a clear eye drop solution. It contains two active substances: travoprost (40 micrograms per millilitre) and timolol (5 mg/ml).

What is DuoTrav used for?

DuoTrav is used to reduce the pressure inside the eye. It is used in adults with 'open angle glaucoma' or 'ocular hypertension' who do not respond sufficiently to eye drops containing beta-blockers or prostaglandin analogues (other medicines used for these conditions).

Ocular hypertension is when the pressure in the eye is higher than normal. In open angle glaucoma the high pressure is caused by fluid being unable to drain out of the eye.

DuoTrav can only be obtained with a prescription.

How is DuoTrav used?

The dose of DuoTrav is one drop in the affected eye(s) once a day, in the morning or evening, at the same time every day. If more than one type of eye drop is being used, each one should be given at least five minutes apart.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

How does DuoTrav work?

When the pressure inside the eye rises, it causes damage to the retina (the light sensitive membrane at the back of the eye) and to the optic nerve that sends signals from the eye to the brain. This can result in serious vision loss and even blindness. By lowering the pressure, DuoTrav reduces the risk of damaging these structures.

DuoTrav contains two active substances, travoprost and timolol, which lower the pressure in the eye in different ways. Travoprost is a prostaglandin analogue (a man-made copy of the natural substance prostaglandin) that works by increasing the drainage of fluid out of the eye. Travoprost on its own has been authorised in the European Union as Travatan since 2001. Timolol is a beta-blocker that works by reducing the production of fluid within the eye. Timolol has been used to treat glaucoma since the 1970's. The combination of the two active substances has an additive effect, reducing the pressure inside the eye more than either medicine alone.

How has DuoTrav been studied?

DuoTrav has been studied in five main studies involving a total of 1,482 patients (aged 18 to 91) with open-angle glaucoma or ocular hypertension. The studies lasted between six weeks and 12 months. One study compared DuoTrav taken in the morning with DuoTrav taken in the evening. Three studies compared DuoTrav with travoprost and timolol either given on their own, or together but as separate eye drops. The fifth was a 12-month study that compared DuoTrav with eye drops containing a combination of latanoprost (another prostaglandin analogue) and timolol.

In all of the studies, the main measure of effectiveness was the change in pressure inside the eye measured in 'millimetres of mercury' (mmHg). In a patient with glaucoma, the eye pressure is usually higher than 21 mmHg.

What benefit has DuoTrav shown during the studies?

DuoTrav reduced the pressure inside the eye by about a third in all of the studies (the average reduction was about 8-10 mmHg).

DuoTrav taken in the evening was as effective as DuoTrav taken in the morning. DuoTrav was more effective at reducing the pressure inside the eye than timolol on its own, or travoprost on its own. It was as effective as the two medicines given as separate eye drops, and as effective as eye drops containing both latanoprost and timolol.

What is the risk associated with DuoTrav?

The most common side effects with DuoTrav (seen in more than 1 patient in 10) are ocular hyperaemia (increased blood supply to the eye, leading to redness) and eye irritation. For the full list of all side effects reported with DuoTrav, see the package leaflet.

DuoTrav should not be used in people who may be hypersensitive (allergic) to travoprost, timolol (and other beta-blockers), or any of the other ingredients. DuoTrav must not be used in people with asthma or severe lung disease, or in people with some heart conditions. It must also not be used in people with severe allergic rhinitis (inflammation of the nasal passages caused by an allergy) and corneal dystrophies (disorders that cause clouding of the cornea, the transparent layer in front of the eye).

DuoTrav contains benzalkonium chloride which is known to discolour soft contact lenses. Therefore, care should be taken by people who wear soft contact lenses. DuoTrav may cause the iris of the eye to change colour (darken) and the eyelashes to thicken, darken or lengthen.

Why has DuoTrav been approved?

The CHMP decided that DuoTrav's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about DuoTrav:

The European Commission granted a marketing authorisation valid throughout the European Union, for DuoTrav to Alcon Laboratories (UK) Limited on 24 April 2006. The marketing authorisation is valid for an unlimited period.

The full EPAR for DuoTrav is available here. For more information about treatment with DuoTrav, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 08-2010.