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EPAR summary for the public

Travatan

travoprost

This is a summary of the European public assessment report (EPAR) for Travatan. 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 Travatan.

What is Travatan?

Travatan is a clear eye drop solution that contains the active substance travoprost.

What is Travatan used for?

Travatan is used to reduce intraocular pressure (pressure inside the eye). It is used in adults who have open-angle glaucoma (a disease where the pressure in the eye rises because fluid cannot drain out of the eye) and in adults with ocular hypertension (when the pressure in the eye is higher than normal). It can also be used in children from two months of age who have ocular hypertension or childhood glaucoma.

The medicine can only be obtained with a prescription.

How is Travatan used?

The dose is one drop of Travatan in the affected eye(s) once a day, preferably in the evening.

If other eye drops are also being used, they should be given at least 5 minutes apart.

How does Travatan work?

When intraocular pressure is raised, 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, Travatan reduces the risk of

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damage. The active substance in Travatan, travoprost, is a prostaglandin analogue (a man-made copy of a prostaglandin, one of a group of substances naturally found in the body). In the eye, prostaglandins increase the drainage of the watery fluid (aqueous humour) out of the eyeball. Travatan acts in the same way and increases the flow of fluid out of the eye. This helps to reduce the pressure inside the eye.

How has Travatan been studied?

Travatan has been studied in 1,989 adult patients in three main studies, lasting between six and 12 months. All three studies compared travoprost with timolol, which is the standard treatment for glaucoma. One of the three trials also included a comparison with latanoprost (another prostaglandin analogue used for glaucoma). . A fourth study also compared the effectiveness of adding Travatan to treatment with timolol (427 patients, six-month duration). In addition, Travatan was compared with timolol in a fifth main study over 3 months, involving 152 children between 2 months and 18 years of age. The main measure of effectiveness in all studies was the reduction in intraocular pressure

What benefit has Travatan shown during the studies?

Travatan was at least as effective as timolol and as effective as latanoprost in reducing intraocular pressure. The combined treatment with Travatan plus timolol produced an additional decrease of intraocular pressure in patients who were not controlled with timolol alone.

What is the risk associated with Travatan?

The most common side effects when using Travatan (seen in more than 1 patient in 10) are ocular hyperaemia (increased blood supply to the eye, leading to eye irritation and redness) and iris hyperpigmentation (darkening of the colour of the iris). There may also be changes to the patient's eyelashes, including increased length, thickness, colour or number of lashes. Side effects reported in children are similar to those seen in adults. For the full list of all side effects and restrictions with Travatan, see the package leaflet.

Why has Travatan been approved?

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

Other information about Travatan

The European Commission granted a marketing authorisation valid throughout the European Union, for Travatan on 27 November 2001.

The full EPAR for Travatan can be found on the Agency's website ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Travatan, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 12-2014.