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Lumigan
bimatoprost

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis for the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Lumigan?
Lumigan is a clear eye drop solution that contains the active substance bimatoprost. It is available in two strengths, 0.1 and 0.3 mg per millilitre.

What is Lumigan used for?
Lumigan is used to reduce the pressure inside the eye. It is used in adults with long-term 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). Lumigan can be used alone or with beta-blocker eye drops (other medicines used for these conditions).
The medicine can only be obtained with a prescription.

How is Lumigan used?
The recommended dose of Lumigan is one drop in the affected eye(s) once a day in the evening. If more than one type of eye drop is being used, each one should be given at least five minutes apart.

How does Lumigan work?
When the pressure inside the eye 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 loss of vision and even blindness. The active substance in Lumigan, bimatoprost, is a prostaglandin analogue (a man-made copy of a natural substance, prostaglandin). In the eye, prostaglandin increases the drainage of the watery fluid (aqueous humour) out of the eyeball. Lumigan acts in the same way and increases the flow of fluid out of the eye. This helps to reduce the pressure inside the eye and the risk of damage.

How has Lumigan been studied?
Lumigan has been studied in adults with glaucoma or ocular hypertension.
Lumigan 0.3 mg/ml used on its own has been compared with timolol (a beta-blocker used to treat glaucoma) in two 12-month studies involving a total of 1,198 patients. Some of these patients carried on receiving the medicines for up to two or three years (379 and 183 patients, respectively). It has also been compared with latanoprost (another prostaglandin analogue used in glaucoma) in a six-month study involving 269 patients. The effect of adding Lumigan 0.3 mg/ml to existing treatment with a beta-blocker eye drop has been compared with that of adding placebo (a dummy eye drop) in one

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study involving 285 patients. Lumigan's effect when added to beta-blocker treatment has also been compared with that of latanoprost in another study in 437 patients.
An additional 12-month study compared Lumigan 0.1 mg/ml with Lumigan 0.3 mg/ml, and with an intermediate strength of 0.125 mg/ml, in 561 patients.
In all of the studies, the main measure of effectiveness was the reduction in eye pressure. Eye pressure is measured in 'millimetres of mercury' (mmHg). In a patient with ocular hypertension or glaucoma, the value is generally higher than 21 mmHg.

What benefit has Lumigan shown during the studies?
Lumigan 0.3 mg/ml on its own was more effective than timolol at reducing eye pressure. This effect was maintained after two or three years of treatment, with an average reduction in eye pressure of between 7.1 and 8.6 mmHg with Lumigan used once a day, compared with 4.6 to 6.4 mmHg with timolol. Lumigan 0.3 mg/ml was also more effective than latanoprost, with patients using Lumigan achieving a reduction in eye pressure of 6.0 to 8.2 mmHg after six months of treatment compared with 4.9 to 7.2 mmHg with latanoprost.
Adding Lumigan 0.3 mg/ml to existing treatment with a beta-blocker was more effective than continuing to use the beta-blocker on its own. After three months, eye pressure was lowered by 7.4 mmHg in the group adding Lumigan, compared with 3.6 mmHg in the group adding placebo. Lumigan was as effective as latanoprost when added to beta-blocker treatment, with reductions in eye pressure of 8.0 and 7.4 mmHg, respectively, after three months.
Lumigan 0.1 mg/ml brought about slightly smaller decreases in IOP than Lumigan 0.3 mg/ml. However, the lower strength formulation was better tolerated and was less likely to cause hyperaemia (redness of the eye).

What is the risk associated with Lumigan?
The most common side effects with Lumigan (seen in more than 1 patient in 10) are conjunctival hyperaemia (increased blood supply to the eye, leading to redness). In addition, the following side effects are also seen in more than 1 patient in 10 using Lumigan 0.3 mg/ml: growth of eyelashes and ocular pruritus (itchy eye). For the full list of all side effects reported with Lumigan, see the Package Leaflet.
Lumigan should not be used in people who may be hypersensitive (allergic) to bimatoprost or any of the other ingredients.
Lumigan contains benzalkonium chloride, which is known to discolour soft contact lenses. Therefore, care should be taken by people who wear soft contact lenses. Because Lumigan 0.1 mg/ml contains higher levels of benzalkonium chloride than Lumigan 0.3 mg/ml, Lumigan 0.1 mg/ml must not be used in people who have had a reaction to a product containing benzalkonium chloride in the past, and had to stop using the product containing it as a result.

Why has Lumigan been approved?
The Committee for Medicinal Products for Human Use (CHMP) decided that Lumigan's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Lumigan:
The European Commission granted a marketing authorisation valid throughout the European Union for Lumigan to Allergan Pharmaceuticals Ireland on 8 March 2002. The marketing authorisation is valid for an unlimited period.

The full EPAR for Lumigan is available here.

This summary was last updated in 12-2009.