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EPAR summary for the public

Ganfort

bimatoprost / timolol

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

What is Ganfort?

Ganfort is an eye drops solution that contains two active substances: bimatoprost (0.3 mg/ml) and timolol (5 mg/ml).

What is Ganfort used for?

Ganfort 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.

The medicine can only be obtained with a prescription.

How is Ganfort used?

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

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How does Ganfort work?

Raised pressure in the eye 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, Ganfort reduces the risk of damage.

Ganfort contains two active substances, bimatoprost and timolol, which lower the pressure in the eye in different ways. Bimatoprost is a prostaglandin analogue, (a copy of the natural substance prostaglandin) that works by increasing the drainage of fluid out of the eye. Bimatoprost on its own has already been approved in the European Union under the name Lumigan. Timolol is a beta-blocker that works by reducing the production of fluid within the eye. Timolol has been commonly used to treat glaucoma since the 1970s. The combination of the two active substances has an additive effect, reducing the pressure inside the eye more than either medicine alone.

How has Ganfort been studied?

Four main studies have been performed involving 1,964 adults with ocular hypertension or glaucoma. The studies compared Ganfort with bimatoprost, timolol, or bimatoprost and timolol given at the same time after three weeks to four months of treatment. The main measures of effectiveness were the average reduction in eye pressure or the number of patients whose eye pressure fell below the target of 18 mmHg (making it within the normal range).

What benefit has Ganfort shown during the studies?

Overall, the studies showed that Ganfort is effective in lowering eye pressure. The values were lowered by about 8-10 mmHg. Ganfort was more effective than timolol on its own and was as effective as bimatoprost.

Ganfort was, however, more effective than bimatoprost in patients whose pressure was not controlled with eye drops containing prostaglandins alone. Ganfort lowered the pressure to less than 18 mmHg in 18.7% of these patients compared with 10.2% with bimatoprost only. In addition, more patients given Ganfort had a drop in pressure of more than 20% (67.9% against 48.9%).

In addition, Ganfort was shown to be as effective as bimatoprost and timolol given at the same time.

What is the risk associated with Ganfort?

The most common side effect (seen in more than 1 patient in 10) is conjunctival hyperaemia (increased blood supply to the eye, leading to redness of the eye). For the full list of all side effects reported with Ganfort, see the package leaflet.

Ganfort must not be used in patients who have asthma or severe lung disease, or in patients with some heart conditions. See the package leaflet for the full list of restrictions.

Why has Ganfort been approved?

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

What measures are being taken to ensure the safe and effective use of Ganfort?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Ganfort have been included in the summary of product characteristics and the package leaflet.

Other information about Ganfort

The European Commission granted a marketing authorisation valid throughout the European Union for Ganfort on 19 May 2006.

The full EPAR for Ganfort 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 Ganfort, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 07-2016.