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EPAR summary for the public

Simbrinza

brinzolamide / brimonidine tartrate

This is a summary of the European public assessment report (EPAR) for Simbrinza. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Simbrinza.

For practical information about using Simbrinza, patients should read the package leaflet or contact their doctor or pharmacist.

What is Simbrinza and what is it used for?

Simbrinza is an eye drop solution that contains two active substances: brinzolamide and brimonidine tartrate. Simbrinza is used to reduce intra-ocular pressure (pressure inside the eye) in adults with ocular hypertension (high intra-ocular pressure) or in those with an eye condition known as open-angle glaucoma.

Simbrinza is used when treatment with other medicines containing only one active substance have been tried but has not reduced the intra-ocular pressure sufficiently.

How is Simbrinza used?

Simbrinza is given as one drop into the affected eye(s) twice a day. If other eye drops are also being used to lower eye pressure, they should be given at least 5 minutes apart.

Simbrinza can only be obtained by prescription. For further information, see the package leaflet.

How does Simbrinza work?

Open-angle glaucoma (a condition where the aqueous humour, the watery fluid inside the eyeball, cannot drain away properly) and other causes of high pressure in the eye increase the risk of damage to the retina and the optic nerve (the nerve that sends signals from the eye to the brain). This can result in serious vision loss and even blindness.

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The active substances in Simbrinza, brinzolamide and brimonidine tartrate, help to reduce intra-ocular pressure by reducing the production of aqueous humour. Brinzolamide works by blocking an enzyme called carbonic anhydrase, which produces bicarbonate needed for the production of the aqueous humour, while brimonidine tartrate blocks another enzyme known as adenylate cyclase, which is also involved in the production of the aqueous humour. Brimonidine also increases the drainage of aqueous humour from the front of the eye.

Both medicines have been used separately to reduce eye pressure for several years in the EU and their combination reduces the pressure inside the eye more effectively than either medicine alone.

What benefits of Simbrinza have been shown in studies?

Simbrinza has been shown to be more effective in reducing eye pressure than either brinzolamide or brimonidine tartrate used alone. One main study involved 560 patients with ocular hypertension or open-angle glaucoma, whose average intra-ocular pressure before treatment, measured in units called mmHg, was 26 mmHg. The reduction in intra-ocular pressure after 3 months was greater in patients using Simbrinza (an average fall of 7.9 mmHg) than in those using either brinzolamide or brimonidine tartrate (6.5 and 6.4 mmHg, respectively).

A second main study involving 890 patients compared Simbrinza with a combination treatment of brinzolamide and brimonidine tartrate given as separate drops. Simbrinza was shown to be as effective as the combination treatment. The average reduction in intra-ocular pressure with Simbrinza after 3 months was 8.5 mmHg compared with 8.3 mmHg with the combination.

What are the risks associated with Simbrinza?

The most common side effects in studies with Simbrinza were ocular hyperaemia (red eye) and allergic reactions in the eye, which occurred in about 6 to 7% of patients, and dysgeusia (taste disturbances) in about 3% of patients. For the full list of all side effects reported with Simbrinza, see the package leaflet.

Simbrinza must not be used in patients who are hypersensitive (allergic) to the active substances, any of the other ingredients, or to sulphonamides (a class of antibiotics). It must also not be used in patients receiving certain types of antidepressants, patients with severely reduced kidney function, or in patients with hyperchloraemic acidosis (excess acid in the blood caused by too much chloride).

Simbrinza must not be used in neonates or children under the age of two years and is not recommended in older children.

Why is Simbrinza approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that Simbrinza was shown to be more effective than either active substance used alone and at least as effective as the combination of the active substances given as separate eye drops. Having the two active substances in one eye drop will improve convenience and adherence to treatment for patients who are not adequately controlled with either brimonidine or brinzolamide alone. It will also benefit those patients who need a combination treatment and for whom previously authorised combinations containing the medicine timolol are not suitable.

As regards safety, the side effects reported with Simbrinza were what would be expected with the individual active substances and raised no major concerns. The CHMP therefore concluded that Simbrinza's benefits are greater than its risks and recommended that it be approved for use in the EU.

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

A risk management plan has been developed to ensure that Simbrinza is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Simbrinza, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the summary of the risk management plan.

Other information about Simbrinza

The European Commission granted a marketing authorisation valid throughout the European Union for Simbrinza on 18 July 2014.

The full EPAR and risk management plan summary for Simbrinza 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 Simbrinza, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 07-2014.