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SCIENCE MEDICINES HEALTH

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Rhokiinsa (*netarsudil*)

An overview of Rhokiinsa and why it is authorised in the EU

What is Rhokiinsa and what is it used for?

Rhokiinsa is an eye-drop solution that is used to reduce pressure inside the eye in adults who have open-angle glaucoma (a disease where the pressure in the eye rises because fluid cannot drain out of the eye) or ocular hypertension (when the pressure in the eye is higher than normal).

Rhokiinsa contains the active substance netarsudil.

How is Rhokiinsa used?

Rhokiinsa is only available on prescription and should be started by an eye specialist. It is available as an eye-drop solution (200 microgram/ml) and the dose is one drop in the affected eye once a day, in the evening.

For more information about using Rhokiinsa, see the package leaflet or contact your doctor or pharmacist.

How does Rhokiinsa work?

When pressure in the eye is raised, it can cause 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.

The active substance in Rhokiinsa, netarsudil, is a Rho kinase inhibitor. This means that it blocks the activity of an enzyme called Rho kinase, which has a role in controlling drainage of fluid from the eye. When it blocks this enzyme, Rhokiinsa increases the flow of fluid out of the eyeball, thereby lowering pressure inside the eye. Rhokiinsa is also thought to lower eye pressure by reducing pressure in the veins around the eyes.

What benefits of Rhokiinsa have been shown in studies?

A main study of 708 patients with open-angle glaucoma or ocular hypertension showed that Rhokiinsa is effective at lowering eye pressure. In patients with moderately high eye pressure (up to 25 mmHg), Rhokiinsa was as effective as timolol (another medicine), lowering the pressure by around 3.9 mmHg to 4.7 mmHg, compared with reductions of 3.8 mmHg to 5.2 mmHg for patients using timolol.

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In patients whose eye pressure was higher than 25 mmHg, Rhokiinsa was less effective than timolol. However, when these results were combined with results from other studies, decreases in eye pressure with Rhokiinsa were larger than those seen in the main study only.

What are the risks associated with Rhokiinsa?

The most common side effect with Rhokiinsa (which may affect around 5 in 10 people) is conjunctival hyperaemia (increased blood supply to the eye, leading to redness). Other common side effects (which may affect up to 2 in 10 people) are: cornea verticillata (deposits in the cornea, the transparent layer in front of the eye that covers the pupil and iris), eye pain, conjunctival haemorrhage (bleeding in the surface layer of the eye), erythema (reddening) at the site where the medicine was applied and the eyelid, corneal staining, blurred vision and increased lacrimation (watery eyes).

For the full list of side effects and restrictions with Rhokiinsa, see the package leaflet.

Why is Rhokiinsa authorised in the EU?

Rhokiinsa, which has a different mode of action from previously authorised treatments, provides another treatment option for patients with open-angle glaucoma and ocular hypertension. Rhokiinsa showed good effects across a range of eye pressures. The effect of Rhokiinsa was less pronounced in patients whose eye pressure was more than 30 mmHg, but these results were considered less important because Rhokiinsa is not expected to be used on its own in this group.

In terms of safety, the side effects of Rhokiinsa are considered manageable and were more likely to be confined to the eye. However, side effects on the eye were more frequent than those of timolol, and this may lead people to stop treatment. The safety of Rhokiinsa will be further investigated in a study.

The European Medicines Agency therefore decided that Rhokiinsa's benefits are greater than its risks and it can be authorised for use in the EU.

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

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

As for all medicines, data on the use of Rhokiinsa are continuously monitored. Side effects reported with Rhokiinsa are carefully evaluated and any necessary action taken to protect patients.

Other information about Rhokiinsa

Rhokiinsa received a marketing authorisation valid throughout the EU on 19 November 2019.

Further information on Rhokiinsa can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/rhokiinsa

This overview was last updated in 11-2019.