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Roclanda (*latanoprost / netarsudil*)

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

What is Roclanda and what is it used for?

Roclanda is an eye-drop solution for reducing 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). It is for patients in whom treatment with either a prostaglandin medicine or netarsudil alone did not sufficiently reduce the pressure.

Roclanda contains the active substances latanoprost and netarsudil.

How is Roclanda used?

The medicine can only be obtained with a prescription and treatment should be started by an eye specialist. It is available as an eye-drop solution and the dose is one drop in the affected eye, in the evening.

For more information about using Roclanda, see the package leaflet or contact your healthcare provider.

How does Roclanda work?

Raised pressure in the eye 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.

Roclanda contains two active substances, netarsudil and latanoprost, which lower the pressure in the eye in different ways. Latanoprost is a prostaglandin analogue (a copy of the natural substance prostaglandin) that works by increasing the drainage of fluid out of the eye. Netarsudil blocks the activity of an enzyme called Rho kinase, which has a role in controlling fluid drainage from the eye. By blocking this enzyme, netarsudil increases the flow of fluid out of the eyeball, thereby lowering pressure inside the eye. Together, the two active substances reduce the pressure inside the eye more than either medicine alone.

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What benefits of Roclanda have been shown in studies?

Two main studies involving a total of 1,468 adults with glaucoma or ocular hypertension showed that Roclanda is more effective at lowering eye pressure than either of its two active substances given alone.

Both studies measured the pressure inside the eye at 9 different time points over a period of 3 months. Taken together, the results from the two studies showed that pressure inside the eye in patients treated with Roclanda was between 15.03 and 16.38 mmHg, compared with between 17.35 and 19.39 mmHg in those treated with netarsudil and between 16.93 and 17.96 mmHg in those treated with latanoprost.

What are the risks associated with Roclanda?

The most common side effects with Roclanda (which may affect more than 1 in 10 people) are conjunctival hyperaemia (red eye), pain at the site where the medicine was applied and cornea verticillata (deposits in the cornea, the transparent layer in front of the eye that covers the pupil and iris).

Other common side effects (which may affect up to 1 in 10 people) are eye pruritus (itching of the eye), erythema (reddening) and discomfort in the eye, increased lacrimation (watery eyes), and conjunctival haemorrhage (bleeding in the surface layer of the eye).

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

Why is Roclanda authorised in the EU?

Roclanda, which combines two medicines to reduce pressure inside the eye, is more effective than the individual medicines given alone. This offers another treatment option for patients with open-angle glaucoma or ocular hypertension in whom a prostaglandin analogue or netarsudil alone have not sufficiently reduced the pressure. Reducing pressure inside the eye can prevent eye pain and loss of vision.

The side effects of Roclanda are generally mild to moderate and considered manageable.

The European Medicines Agency decided that Roclanda'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 Roclanda?

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

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

Other information about Roclanda

Roclanda received a marketing authorisation valid throughout the EU on 07 January 2021.

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

This overview was last updated in 01-2021.