swissmedic

Public Summary SwissPAR dated 1 February 2024

Roclanda® (active substances: latanoprost, netarsudil)

First authorisation in Switzerland: 3 October 2023

Medicinal product (eye drops) to reduce elevated intraocular pressure in adults.

Information on authorisation

The medicinal product Roclanda contains the active ingredients latanoprost and netarsudil and is administered as drops into the eyes as a solution.

Roclanda is used in adults to reduce elevated intraocular pressure. Patients have primary open-angle glaucoma (condition in which the pressure in the eye increases as the fluid is unable to drain from the eye) or ocular hypertension (when the pressure in the eye is higher than normal). They have previously been treated with a prostaglandin[1], resulting in an insufficient reduction in intraocular pressure.

In deciding whether to authorise the medicinal product Roclanda, Swissmedic took into account the assessments of the European Medicines Agency (EMA), the US Food and Drug Administration (FDA) and the corresponding medicinal product information texts.

Since the assessment of the clinical data was based on the assessment reports of these foreign authorities, the preconditions for a SwissPAR (Swiss Public Assessment Report – a detailed report for professionals) and a resulting Public Summary SwissPAR are not met. Swissmedic refers to the authorisations of the foreign reference authorities.

www.ema.europa.eu

www.fda.gov

[1] Prostaglandin therapy: Prostaglandin medications are structurally or functionally similar to the hormone prostaglandin produced naturally in the body, which is involved in various pain and inflammation reactions. Prostaglandin therapy triggers increased drainage of fluid from the eye, resulting in a reduction in intraocular pressure.

Further information on the medicinal product

At the time of publication of the Public Summary SwissPAR for Roclanda, the Information for healthcare professionals was not yet available. As soon as the medicinal product becomes available in Switzerland, the Information for healthcare professionals will be made available on the following website: www.swissmedicinfo.ch

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.