Medicines & Healthcare products
Regulatory Agency

Public Assessment Report

National Procedure

Latanoprost 50 micrograms/ml eye drops, solution

latanoprost

PL 47848/0052

Axunio Pharma GmbH

LAY SUMMARY

Latanoprost 50 micrograms/ml eye drops, solution
latanoprost

This is a summary of the Public Assessment Report (PAR) for Latanoprost 50 micrograms/ml eye drops, solution. It explains how this product was assessed and its authorisation recommended, as well as its conditions of use. It is not intended to provide practical advice on how to use this product.

This product will be referred to as Latanoprost in this lay summary for ease of reading.

This application was approved under International Recognition procedure (IRP). The Reference Regulator (RR) was the EU/EEA (Czech Republic), with the procedure number (CZ/H/0763/001/DC). The procedure followed route B.

This application was approved under Regulation 52B of the Human Medicines Regulation 2012, as amended (previously Article 10.3 of Directive 2001/83/EC, as amended).

For practical information about using Latanoprost, patients should read the Patient Information Leaflet (PIL) or contact their doctor or pharmacist.

What is Latanoprost and what is it used for?
This application is for a hybrid medicine. This means that the medicine is similar to a reference medicine already authorised, called Xalatan 50 micrograms/ml Eye Drops Solution.

Latanoprost is used to treat conditions known as open angle glaucoma and ocular hypertension in adults. Both of these conditions are linked with an increase in the pressure within the eye, eventually affecting a person's eye sight.

Latanoprost is also used to treat increased eye pressure and glaucoma in all ages of children and babies.

How does Latanoprost work?
Latanoprost belongs to a group of medicines known as prostaglandin analogues. It works by increasing the natural outflow of fluid from inside the eye into the bloodstream.

How is Latanoprost used?
The pharmaceutical form of this medicine is an eye drops solution and the route of administration is ocular use (onto the surface of the eye).

The recommended dosage for adults (including the elderly) and children is one drop once a day in the affected eye(s). The best time to do this is in the evening.

The patient should not use Latanoprost more than once a day, because the effectiveness of the treatment can be reduced if they administer it more often.

The patient should use Latanoprost as instructed by their doctor or by the doctor treating their child until they tell them to stop.

Contact lens wearers
If the patient or their child wears contact lenses, they should be removed before using Latanoprost. After using Latanoprost the patient should wait 15 minutes before putting the contact lenses back into the eyes.

Instructions for use
1. The patient should wash their hands and sit or stand comfortably.
2. Twist off the cap.
3. The patient should use their finger to gently pull down the lower eyelid of their affected eye.
4. Place the tip of the bottle close to, but not touching the eye. Squeeze the bottle gently so that only one drop goes into the eye.
5. Release the lower eyelid.
6. Press a finger against the corner of the affected eye by the nose. Hold for 1 minute whilst keeping the eye closed.
7. The patient should repeat steps 3-6 in the other eye if the doctor has told them to do this.
8. Replace cap on the bottle.

If the patient uses Latanoprost with other eye drops
The patient should wait at least 5 minutes between using Latanoprost and taking other eye drops.

For further information on how Latanoprost is used, refer to the PIL and Summary of Product Characteristics (SmPC) available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

This medicine can only be obtained with a prescription.

The patient should always take the medicine exactly as their doctor/pharmacist has told them. The patient should check with their doctor or pharmacist if they are not sure.

What benefits of Latanoprost have been shown in studies?
No additional studies were needed as Latanoprost contains the same active substance as the reference medicine, and satisfactory data to justify the differences have been provided.

What are the possible side effects of Latanoprost?
For the full list of all side effects reported with this medicine, see Section 4 of the PIL or the SmPC available on the MHRA website.

If a patient gets any side effects, they should talk to their doctor, pharmacist or nurse. This includes any possible side effects not listed in the product information or the PIL that comes with the medicine. Patients can also report suspected side effects themselves, or a report can be made on their behalf by someone else who cares for them, directly via the Yellow Card scheme at https://yellowcard.mhra.gov.uk or search for 'MHRA Yellow Card' online. By reporting side effects, patients can help provide more information on the safety of this medicine.

Because Latanoprost is a hybrid medicine and is therapeutically equivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

Why was Latanoprost approved?
It was concluded that Latanoprost has been shown to be therapeutically equivalent to the reference medicine. Therefore, the MHRA decided that, as for the reference medicine, the benefits are greater than the risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Latanoprost?
As for all newly-authorised medicines, an Risk Management Plan (RMP) has been developed for Latanoprost. The RMP details the important risks of Latanoprost, how these risks can be minimised, any uncertainties about Latanoprost (missing information), and how more information will be obtained about the important risks and uncertainties.

The following safety concerns have been recognised for Latanoprost:

Summary of safety concerns	
Important identified risks	• None
Important potential risks	• Aggravation of asthma • Central corneal thickness
Missing information	• Ocular tolerability in paediatric population
	• Long-term safety in paediatric patients (including ocular developmental and neurodegenerative events, hyperpigmentation changes in the eye, and corneal endothelial function/corneal thickness) • Limited information on drug interactions in adult and paediatric patients • Use in pregnant and lactating women

The information included in the SmPC and the PIL is compiled based on the available quality, non-clinical and clinical data, and includes appropriate precautions to be followed by healthcare professionals and patients. Side effects of Latanoprost are continuously monitored and reviewed including all reports of suspected side-effects from patients, their carers, and healthcare professionals.

An RMP and a summary of the pharmacovigilance system have been provided with this application and are satisfactory.

Other information about Latanoprost
A marketing authorisation was granted in the United Kingdom on 7 April 2025.

The full PAR for Latanoprost follows this summary.

This summary was last updated in May 2025.

TABLE OF CONTENTS

I. INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the Medicines and Healthcare products Regulatory Agency (MHRA) considered that the application for Latanoprost 50 micrograms/ml eye drops (PL 47848/0052) could be approved.

The product is approved for the following indications:

- Reduction of elevated intraocular pressure (IOP) in patients with open angle glaucoma and ocular hypertension in adults (including elderly).
- Reduction of elevated IOP in paediatric patients with elevated IOP and paediatric glaucoma.

The active substance latanoprost, a prostaglandin F2α analogue, is a selective prostanoid FP receptor agonist which reduces the IOP by increasing the outflow of aqueous humour. Reduction of the IOP in man starts about three to four hours after administration and maximum effect is reached after eight to twelve hours. Pressure reduction is maintained for at least 24 hours.

This application was approved under International Recognition procedure (IRP). The Reference Regulator (RR) was the EU/EEA (Czech Republic), with the procedure number (CZ/H/0763/001/DC).

For the scientific discussion of the quality, non-clinical and clinical assessment conducted by the reference regulator, please refer to the public assessment report on the relevant competent authority's website.

This application was approved under Regulation 52B of the Human Medicines Regulation 2012, as amended (previously Article 10.3 of Directive 2001/83/EC, as amended).

The MHRA has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place for this product at all sites responsible for the manufacture, assembly and batch release of this product.

A Risk Management Plan (RMP) and a summary of the pharmacovigilance system have been provided with this application and are satisfactory.

A marketing authorisation was granted on 7 April 2025.

II. PRODUCT INFORMATION

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

The SmPC is in line with current guidelines and is satisfactory.

PATIENT INFORMATION LEAFLET (PIL)

The PIL is in line with current guidelines and is satisfactory.

LABEL

The labelling is in line with current guidelines and is satisfactory.

III. QUALITY ASPECTS

MHRA considered that the quality data submitted for this application is satisfactory.

The grant of a marketing authorisation was recommended.

IV. NON-CLINICAL ASPECTS

MHRA considered that the non-clinical data submitted for this application is satisfactory.

The grant of a marketing authorisation was recommended.

V. CLINICAL ASPECTS

MHRA considered that the clinical data submitted for this application is satisfactory.

The grant of a marketing authorisation was recommended.

VI. RISK MANAGEMENT PLAN (RMP)

The applicant has submitted an RMP, in accordance with the requirements of Regulation 182 of The Human Medicines Regulation 2012, as amended. The applicant proposes only routine pharmacovigilance and routine risk minimisation measures for all safety concerns. This is acceptable.

VII. USER CONSULTATION

A text draft of the Patient Information Leaflet (PIL) was presented. A commitment to provide a mock-up and evidence of user consultation of the PIL to the MHRA prior to marketing was accepted.

VIII. OVERALL CONCLUSION, BENEFIT/RISK AND RECOMMENDATION

The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified. The benefit/risk balance is, therefore, considered to be positive.

The Summaries of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and labelling are satisfactory.

In accordance with legal requirements, the current approved UK versions of the SmPC and PIL for this product are available on the MHRA website.

IX. TABLE OF CONTENT OF THE PAR UPDATE

Steps taken after the initial procedure with an influence on the Public Assessment Report (non-safety variations of clinical significance).

Please note that only non-safety variations of clinical significance are recorded below and in the annexes to this PAR. The assessment of safety variations, where significant changes are made, are recorded on the MHRA website or European Medicines Agency (EMA) website. Minor changes to the marketing authorisation are recorded in the current SmPCs and/or PIL available on the MHRA website.

Application type	**Scope**	**Product information affected**	**Date of grant**	**Outcome**	**Assessment report attached Y/N**