Medicines & Healthcare products
Regulatory Agency

Public Assessment Report

National Procedure

Dorzolamide 20 mg/ml eye drops, solution dorzolamide (as dorzolamide hydrochloride)

PL 14251/0325

Manx Healthcare Limited

LAY SUMMARY

Dorzolamide 20 mg/ml eye drops, solution
dorzolamide (as dorzolamide hydrochloride)

This is a summary of the Public Assessment Report (PAR) for Dorzolamide 20 mg/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 Dorzolamide eye drops solution in this lay summary for ease of reading.

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

What is Dorzolamide eye drops solution 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 Trusopt 20 mg/ml eye drops, solution.

This medicine is prescribed to lower raised pressure in the eye and to treat glaucoma.

This medicine can be used alone or in addition to other medicines which lower the pressure in the eye (so-called beta-blockers).

How does Dorzolamide eye drops solution work?
Dorzolamide eye drops, solution contains the active substance dorzolamide (as dorzolamide hydrochloride), which belongs to a group of medicines called “carbonic anhydrase inhibitors”. This medicine is prescribed to lower raised pressure in the eye and to treat glaucoma.

How is Dorzolamide eye drops solution used?
The pharmaceutical form of this medicine is an eye drops, solution and the route of administration is instillation in the eye.

The appropriate dosage and duration of treatment will be established by the patient’s doctor.

When this medicine is used alone, the recommended dose is one drop in the affected eye(s) in the morning, in the afternoon and in the evening.

If the patient’s doctor has recommended the patient uses this medicine with a beta-blocker eye drop to lower eye pressure, then the recommended dose is one drop of Dorzolamide eye drops solution in the affected eye(s) in the morning and in the evening.

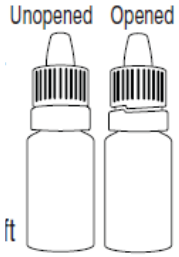
If the patient is using Dorzolamide eye drops solution with another eye drop, the drops should be instilled at least 10 minutes apart.

The patient should not allow the tip of the container to touch the eye or areas around the eye. It may become contaminated with bacteria that can cause eye infections leading to serious damage of the eye, even loss of vision.

To avoid possible contamination, the patient should wash their hands before using this medicine and keep the tip of the container away from contact with any surface. If the patient thinks that the medication may be contaminated, or if they develop an eye infection, they should contact their doctor immediately concerning continued use of this container.

Instructions for use

1. First wash the hands.
2. Before opening the bottle for the first time, make sure the tamper-evidence ring of the cap is intact.
3. To open the bottle, unscrew the cap by turning it to the left (anticlockwise). The patient should feel a slight resistance until this tamper evidence.



4. Tilt the head back and pull the lower eyelid down slightly to form a “pocket” between the eyelid and the eye.

5. Invert the bottle and press lightly with the thumb or index finger over the “Finger Push Area” until a single drop is dispensed into the eye as directed by the doctor. DO NOT TOUCH the EYE OR EYELID WITH THE DROPPER TIP.

6. Close the eye and press the inner corner of the eye with the finger for about two minutes. This helps to stop the medicine from getting into the rest of the body.

7. If drop dispensing is difficult after opening for the first time, replace the cap on the bottle and tighten (do not over tighten) and then remove by turning the cap in the opposite direction as indicated by the arrows on the top of the cap.

8. Repeat steps 4, 5 and 6 with the other eye if instructed to do so by the doctor.

9. Replace the cap by turning until it is firmly touching the bottle. The arrow on the left side of the cap must be aligned with the arrow on the left side of the bottle label for proper closure.
10. The dispenser tip is designed to provide a single drop; do NOT enlarge the hole of the dispenser tip.
11. After dispensing all doses, a small amount of the medicine will remain in the bottle. The patient should not be concerned because an extra amount of Dorzolamide eye drops solution has been added, and they have used the full amount of Dorzolamide eye drops solution that the doctor prescribed. Do not attempt to remove the excess medicine from the bottle.

For further information on how Dorzolamide eye drops solution 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 this 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 Dorzolamide eye drops solution have been shown in studies?
No additional studies were needed as Dorzolamide eye drops solution 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 Dorzolamide eye drops solution?
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.

As Dorzolamide eye drops solution 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 Dorzolamide eye drops solution approved?
It was concluded that Dorzolamide eye drops solution 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 Dorzolamide eye drops solution?
As for all newly authorised medicines, a Risk Management Plan (RMP) has been developed for Dorzolamide eye drops solution. The RMP details the important risks of Dorzolamide eye drops solution, how these risks can be minimised, any uncertainties about Dorzolamide eye

drops solution (missing information), and how more information will be obtained about the important risks and uncertainties.

There are no safety concerns, with respect to the RMP, associated with use of Dorzolamide eye drops solution.

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 Dorzolamide eye drops solution 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 Dorzolamide eye drops solution
A marketing authorisation for Dorzolamide eye drops solution was granted in the United Kingdom (UK) on 30 October 2025.

The full PAR for Dorzolamide eye drops solution follows this summary.

This summary was last updated in December 2025.

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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 Dorzolamide 20 mg/ml eye drops, solution (PL 14251/0325) could be approved.

The product is approved for the following indications:

- as adjunctive therapy to beta-blockers,
- as monotherapy in patients unresponsive to beta-blockers or in whom beta- blockers are contraindicated,
- in the treatment of elevated intra-ocular pressure in:
  - ocular hypertension,
  - open-angle glaucoma,
  - pseudo-exfoliative glaucoma.

The product contains the active substance dorzolamide (as dorzolamide hydrochloride), which is a potent inhibitor of human carbonic anhydrase II (CA-II).

Carbonic anhydrase (CA) is an enzyme found in many tissues of the body including the eye. In humans, carbonic anhydrase exists as a number of isoenzymes, the most active being CA-II found primarily in red blood cells (RBCs) but also in other tissues. Inhibition of carbonic anhydrase in the ciliary processes of the eye decreases aqueous humour secretion. The result is a reduction in intra-ocular pressure (IOP).

Following topical ocular administration, dorzolamide reduces elevated intra-ocular pressure, whether or not associated with glaucoma. Elevated intra-ocular pressure is a major risk factor in the pathogenesis of optic nerve damage and visual-field loss. Dorzolamide does not cause pupillary constriction and reduces intra-ocular pressure without side effects such as night blindness, accommodative spasm. Dorzolamide has minimal or no effect on pulse rate or blood pressure.

Topically applied beta-adrenergic blocking agents also reduce IOP by decreasing aqueous humour secretion but by a different mechanism of action. Studies have shown that when dorzolamide is added to a topical beta-blocker, additional reduction in IOP is observed; this finding is consistent with the reported additive effects of beta- blockers and oral carbonic anhydrase inhibitors.

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), claiming to be a hybrid medicinal product of a suitable originator product, Trusopt 20 mg/mL eye drops, solution that has been licensed for a suitable time, in line with the legal requirements.

No new non-clinical studies were conducted, which is acceptable given that the application is for a hybrid medicinal product of a suitable reference product.

A biowaiver was submitted with this application which was accepted. No bioequivalence or therapeutic equivalence studies were required and none were provided with this application.

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.

Advice was sought from the Commission of Human Medicines (CHM) on 21 November 2025; following provision of additional data the marketing authorisations was considered approvable.

A national marketing authorisation was granted in the United Kingdom (UK) 30 October 2025.

II QUALITY ASPECTS

II.1 Introduction

This product contain 22.26 mg of dorzolamide hydrochloride equivalent to 20 mg of dorzolamide in each ml of eye drops solution.

In addition to dorzolamide (as dorzolamide hydrochloride), this product also contains the excipients benzalkonium chloride, hydroxyethylcellulose, mannitol (E421), sodium citrate (E331), sodium hydroxide solution (E524) for pH adjustment and water for injections.

The finished product is packaged in in white low-density polyethylene (LDPE) bottles, each with a white LDPE dropper and white high-density polyethylene (HDPE) screw cap.
Each dropper container contains 5 ml of Dorzolamide 20 mg/ml eye drops, solution. Each packaging contains: 1 dropper container.

Satisfactory specifications and Certificates of Analysis have been provided for all packaging components. All primary packaging complies with the current regulations concerning materials in contact with food.

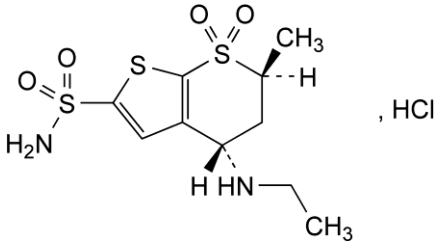
II.2 ACTIVE SUBSTANCE

rINN: Dorzolamide hydrochloride

Chemical Name: (4S,6S)-4-(Ethylamino)-6-methyl-5,6-dihydro-4H-thieno[2,3-b]thiopyran-2-sulfonamide 7,7-dioxide hydrochloride

Molecular Formula: $C_{10}H_{17}ClN_2O_4S_3$

Chemical Structure:



Molecular Weight: 360.9 g/mol

Appearance: White or almost white, crystalline powder

Solubility: Soluble in water, slightly soluble in methanol, very slightly soluble in anhydrous ethanol

Dorzolamide hydrochloride is the subject of a European Pharmacopoeia monograph.

All aspects of the manufacture and control of the active substance are covered by a European Directorate for the Quality of Medicines and Healthcare (EDQM) Certificate of Suitability.

II.3 DRUG PRODUCT

Pharmaceutical development

A satisfactory account of the pharmaceutical development has been provided.

All excipients comply with their respective European/national pharmacopoeial monographs.

Satisfactory Certificates of Analysis have been provided for all excipients.

No excipients of animal or human origin are used in the finished product.

This product does not contain or consist of genetically modified organisms (GMO).

Manufacture of the product

A description and flow-chart of the manufacturing method has been provided.

Satisfactory batch formulation data have been provided for the manufacture of the product, along with an appropriate account of the manufacturing process. The manufacturing process has been validated and has shown satisfactory results.

Finished Product Specifications

The finished product specifications at release and shelf-life are satisfactory. The test methods have been described and adequately validated. Batch data have been provided that comply with the release specifications. Certificates of Analysis have been provided for any working standards used.

Stability

Finished product stability studies have been conducted in accordance with current guidelines, using batches of the finished product stored in the packaging proposed for marketing. Based on the results, a shelf-life of 2 years before first opening and within 28 days after first opening the product, with the storage conditions ‘This medicinal product does not require any special temperature storage conditions. Keep the bottle in the outer carton in order to protect from light.’, is acceptable.

Suitable post approval stability commitments have been provided to continue stability testing on batches of finished product.

II.4 Discussion on chemical, pharmaceutical and biological aspects

The grant of a marketing authorisation is recommended.

III NON-CLINICAL ASPECTS

III.1 Introduction

As the pharmacodynamic, pharmacokinetic and toxicological properties of dorzolamide are well-known, no new non-clinical studies are required, and none have been provided. An overview based on the literature review is, thus, appropriate.

III.2 Pharmacology

No new pharmacology data were provided and none were required for this application.

III.3 Pharmacokinetics

No new pharmacokinetic data were provided and none were required for this application.

III.4 Toxicology
No new toxicology data were provided and none were required for this application.

III.5 Ecotoxicity/Environmental Risk Assessment
Suitable justification has been provided for non-submission of an Environmental Risk Assessment. As this is a hybrid application of an already authorised product, it is not expected that environmental exposure will increase following approval of the marketing authorisation for the proposed product.

III.6 Discussion on the non-clinical aspects
The grant of a marketing authorisation is recommended.

IV CLINICAL ASPECTS

IV.1 Introduction

In accordance with the regulatory requirements, the applicant has provided a suitable biowaiver. No bioequivalence or therapeutic equivalence studies have been submitted with this application.

IV. 2 Pharmacokinetics
No new pharmacokinetic data have been submitted for this application and none were required.

IV.3 Pharmacodynamics
No new pharmacodynamic data have been submitted for this application and none were required.

IV.4 Clinical efficacy
No new safety data were submitted with this application and none were required. The safety profile for this product is considered to be the same as Trusopt 20 mg/mL eye drops, solution.

IV.6 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.

IV.7 Discussion on the clinical aspects
The grant of a marketing authorisation is recommended for this application.

V USER CONSULTATION

A full colour mock-up of the Patient Information Leaflet (PIL) was provided with the application in accordance with legal requirements, including user consultation.

VI OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified.

Extensive clinical experience with dorzolamide is considered to have demonstrated the therapeutic value of the product.

The benefit/risk is, therefore, considered to be positive.

The Summary of Product Characteristics (SmPC), PIL and labelling are satisfactory and in line with current guidelines.

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

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 SmPC and/or PIL available on the MHRA website.

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