



# **Public Assessment Report**

## **National Procedure**

**Atropine Sulphate 1% w/v eye drops solution in  
single dose container**

**atropine sulphate monohydrate**

**PL 51463/0162**

**Kent Pharma UK Limited**

## LAY SUMMARY

### **Atropine Sulphate 1% w/v eye drops solution in single dose container atropine sulphate monohydrate**

This is a summary of the Public Assessment Report (PAR) for Atropine Sulphate 1% w/v eye drops solution in single dose container . It explains how this product was assessed and its/their 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 Atropine Eye Drops in this lay summary for ease of reading.

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

#### **What are Atropine Eye Drops and what are they used for?**

This application is for a hybrid medicine. This means that the medicine is similar to a reference medicine already authorised, called Minims Atropine Sulphate 1% (PL 03468/0068). In this case, Atropine Eye Drops differs from the reference product, for the shelf life.

Atropine Eye Drops is used in children, adults and the elderly to enlarge the pupil of the patient's eye.

#### **How does Atropine Eye Drops work?**

Atropine Eye Drops contain a mydriatic and cycloplegic agent. They temporarily dilate (widen) the pupil.

#### **How are Atropine Eye Drops used?**

The pharmaceutical form of this medicine is sterile, single-use eye drops, and the route of administration is instilled into the eye.

The drops are for single use only and provided in single dose containers, to treat both eyes if necessary. Once opened, Atropine Eye Drops should be used immediately, and any unused portion should be discarded.

The normal dose is one drop in each eye. If necessary, the patient's doctor or eye specialist will tell the patient to use more than one drop.

The drops are for single use only and are provided in single dose containers, to treat both eyes if necessary.

The doctor or eye specialist will normally put the drops in the patients eye, but if the patient is putting the eye drops in themselves, then the patient must refer directly to the PIL and Summaries of Product Characteristics (SmPCs) available on the Medicines and Healthcare products Regulatory Agency (MHRA) website, for information on the how Atropine eye drops is used.

For further information on how Atropine Eye Drops 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.

The patient should ask the administering healthcare practitioner if they have any questions concerning their medicine.

**What benefits of Atropine Eye Drops have been shown in studies?**

No additional studies were needed as Atropine Eye Drops contain 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 Atropine Eye Drops?**

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 Atropine Eye Drops 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 Atropine Eye Drops approved?**

It was concluded that Atropine Eye Drops 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 Atropine Eye Drops?**

As for all newly-authorized medicines, a Risk Management Plan (RMP) has been developed for Atropine Eye Drops. The RMP details the important risks of Atropine Eye Drops, how these risks can be minimised, any uncertainties about Atropine Eye Drops (missing information), and how more information will be obtained about the important risks and uncertainties.

The following safety concerns have been recognised for Atropine Eye Drops:

<b>Summary of safety concerns</b>	
<b>Important identified risks</b>	<ul style="list-style-type: none"><li>• Hypersensitivity</li><li>• Use in patients with closed angle glaucoma</li><li>• Use in patients with narrow angle between the iris and cornea</li><li>• Impaired vision</li></ul>
<b>Important potential risks</b>	<ul style="list-style-type: none"><li>• Use in patients with raised intra ocular pressure</li><li>• Use in patients with a high ambient temperature or fever</li><li>• Use in patients wearing soft contact lenses</li><li>• Use in patients with conditions characterised by tachycardia</li><li>• Overdose</li></ul>
<b>Missing information</b>	<ul style="list-style-type: none"><li>• Use during pregnancy and lactation</li></ul>

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 Atropine Eye Drops 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 Atropine Eye Drops**

A Marketing Authorisation for Atropine Eye Drops was granted in the United Kingdom (UK) on 10 October 2025.

The full PAR for Atropine Eye Drops follows this summary.

This summary was last updated in October 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 Atropine Sulphate 1% w/v eye drops solution in single dose container (PL 51463/0162) could be approved.

The product is approved for the following indication(s):  
As a topical mydriatic and cycloplegic

The name of the active substance is atropine sulphate which belongs to the pharmacotherapeutic group of anticholinergic agents.

Atropine sulphate is a competitive antagonist of acetylcholine at postganglionic cholinergic (parasympathetic) nerve endings. Atropine does not discriminate between the recently discovered muscarinic receptor sub types M1 (in parasympathetic ganglia of the submucous plexus, with high affinity for selecting antimuscarinic pirenzepine) and M2 (low affinity for pirenzepine and occurring predominantly in heart and smooth muscle).

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, Minims Atropine Sulphate 1% (PL 03468/0068) 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 23 January 2025, following provision of additional data the CHM were reassured on the quality of the product.

A national marketing authorisation was granted in the United Kingdom (UK) on 10 October 2025.

## II QUALITY ASPECTS

### II.1 Introduction

This product consists of preservative free (PF), clear, colourless, sterile eye drops containing Atropine Sulphate Ph.Eur 1% w/v.

In addition to atropine sulphate monohydrate, this product also contains the excipients hydrochloric acid for pH adjustment, sodium hydroxide for pH adjustment and Water for injections.

The finished product is packaged in low density polyethylene single-dose units, containing 0.5 ml solution each. Each strip of 5 single dose containers is packed in a PET/Alu/PE sachet. The box contains 20 single dose containers.

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(S)

#### INN: atropine sulphate monohydrate

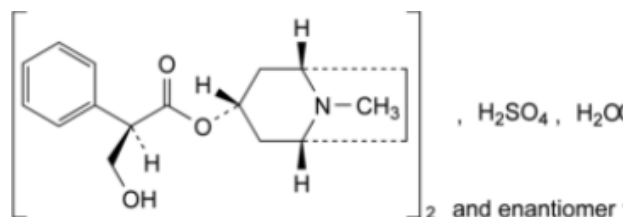
Chemical Name: Ph. Eur. Bis[(1R,3r,5S)-8-methyl-8-azabicyclo[3.2.1]oct-3-yl(2RS)-3-hydroxy-2-phenylpropanoate] sulfate monohydrate

USP. 1 $\alpha$ H,5 $\alpha$ H-Tropan-3- $\alpha$ -ol ( $\pm$ )-tropate (ester), sulfate (2:1) (salt) monohydrate

in house (3-endo)-8-Methyl-8-azabicyclo[3.2.1]oct-3-yl-3-hydroxy-2-phenylpropanoate sulfate (1:1)

Molecular Formula: C<sub>34</sub>H<sub>48</sub>N<sub>2</sub>O<sub>10</sub>S, H<sub>2</sub>O

Chemical Structure:



Molecular Weight: Mr = 695

Appearance: White or almost white, crystalline powder or colourless crystals

Solubility: Very soluble in water, freely soluble in ethanol (96 per cent)

Atropine sulphate monohydrate 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.

Suitable specifications have been provided for all packaging used. The primary packaging complies with the current regulations concerning materials in contact with food.

### II.3 DRUG PRODUCT(S)

#### Pharmaceutical development

A satisfactory account of the pharmaceutical development has been provided.

Comparative *in vitro* impurity profiles have been provided for the proposed and reference products.

All excipients comply with either their respective European/national monographs, or a suitable in-house specification. 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(s)**

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 24 months, with the storage conditions, store below 25°C, do not freeze, keep the single-dose containers in their sachet in order to protect from light and use them within 30 days, is acceptable.

## **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 atropine sulphate monohydrate is 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 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(s) is recommended.

## **IV CLINICAL ASPECTS**

### **IV.1 Introduction**

In accordance with the regulatory requirements, the applicant has provided a suitable bio waiver. 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 efficacy data have been submitted for this application and none were required.

### **IV.5 Clinical safety**

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 Minims Atropine Sulphate 1%.

### **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 atropine sulphate monohydrate 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), Patient Information Leaflet (PIL) and labelling are satisfactory and in line with current guidelines and is consistent with the reference product.

In accordance with legal requirements, the current approved versions of the SmPCs and PILs for these products 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.

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