



Graphics&Packing Technology Section ICN POLFA RZESZÓW S.A.		ULOTKA PIL		<b>BAUSCH + LOMB</b>	
Nazwa produktu Product Name	<b>Minims Atropine sulfat 1 % w/v SOL DRP</b>		Kolor nadruku Colours		
			Black		
Kraj Country (ISO)	UK, IE, MT		Nr wykojnika Spec No	5338_F	
Opracowane przez Designed by	Łukasz Kozioł lukasz.kozioł@valeant.com Phone: +48 17 865 5537		Kod Wytwórcy Manufacturer code	77174	
Nr korekty Proof No	1	Data Date	27.11.2019		Kod farmaceutyczny Pharmacode
					-
Kod wersji Valeant version code	P1UKIE03		Inny kod Other code	77174 (Data Matrix)	
Rozmiar czcionki Font size	minimum 8 pt		Wymiar ulotki PIL size	160 x 240 mm	
Krój czcionki Font used	Frutiger Neue LT W1G Condensed Frutiger Neue LT W1G Condensed Bold		Gramatura papieru Paper weight	60 g/m <sup>2</sup>	
Komentarze Comments (Reason for the change)					
creating a shared pack for UK and Ireland PMR_ICN-19-1132-A Packing Site: Laboratoire Chauvin / Bausch & Lomb					
Akceptacja Techniczna Technical Approval					
<div style="border: 1px dashed black; width: 90%; margin: 0 auto; height: 60px;"></div>					
Akceptacja Działu ds. Rejestracji Regulatory Affairs Dept. Approval					
<div style="border: 1px dashed black; width: 90%; margin: 0 auto; height: 60px;"></div>					

**BAUSCH + LOMB**

# Minims® Atropine Sulphate 1%

## Eye Drops, solution

### Atropine sulphate

Read all this leaflet carefully **before** you start using your medicine. It contains a summary of the information available on your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist. Remember this medicine is for you. Do not give it to someone else.

**In this leaflet:**

1. What Minims® Atropine Sulphate eye drops are and what they are used for
2. Before you use your eye drops
3. How to use your eye drops
4. Possible side effects
5. How to store your eye drops
6. Further information

### 1. What Minims® Atropine Sulphate eye drops are and what they are used for

Minims® Atropine Sulphate contains a mydriatic and cycloplegic agent. It is used to enlarge the pupil of your eye. Your doctor or eye specialist may use it to examine your eye more closely, or as part of a treatment program.

This medicine is indicated for children, adults and the elderly.

### 2. Before you use your eye drops

**Do not use these drops if**

- you are allergic to the active substance (atropine sulphate) or any of the ingredients (refer to the end of this leaflet).
- you have history of closed angle glaucoma (with your eyes likely to develop sudden increased internal pressure when the pupil is enlarged).

**If you are pregnant, may be pregnant, or are breastfeeding**

Tell your doctor or eye specialist, he/she may decide to use these drops or to prescribe you an alternative.

**Contact lenses**

Your doctor will ask you to remove your contact lenses prior to the administration of the drops. Do not wear your contact lenses until the effects of the drops have completely worn off.

**Driving and using machines**

As with all eye drops, your vision may be blurred after putting the drops in. Wait until your vision is clear before driving or using machines.

### 3. How to use your eye drops

The drops are for single use only and provided in single use Minims units, to treat both eyes if necessary. Once opened, use immediately. Discard any unused portion.

**Dosage**



The normal dose is one drop in each eye. If necessary, your doctor or eye specialist will tell you to use more than one drop.

**Method of administration**

The doctor or eye specialist will normally put the drops in your eye for you, but if you are putting the eye drops in yourself, then follow these instructions carefully:

1. Wash your hands.
2. Use a mirror, this will help you to see what you are doing.
3. Carefully dry your eyes using a tissue, and twist off the cap from the Minims body of the unit.
4. Pull your lower eyelid down gently, and then carefully place 1 drop inside your lower eyelid.
5. Close your eye and blink a few times to make sure your eye is covered by the liquid.
6. Close the eyelids. It is advisable to press gently on the inner corner of your eyelid for 3 minutes. This will help stop the solution draining into your nose and throat. This is especially advisable in children, the elderly and population at risk.
7. Repeat steps 4, 5 and 6 for the other eye if necessary, then throw away the Minims unit, even if some solution remains.

**If you use more Minims® Atropine Sulphate than you should**, an overdose is very unlikely to occur. If you suddenly feel unwell after receiving the drops, tell your doctor or eye specialist or contact your nearest emergency department immediately.

Graphics&Packing Technology Section ICN POLFA RZESZÓW S.A.		ULOTKA PIL		<b>BAUSCH + LOMB</b>	
Nazwa produktu Product Name	Minims Atropine sulfate 1 % w/v SOL DRP	Kolor nadruku Colours			
		Black			
Kraj Country (ISO)	UK, IE, MT	Nr wykojnika Spec No	5338_F		
Opracowane przez Designed by	Lukasz Kozioł lukasz.kozioł@valeant.com Phone: +48 17 865 5537	Kod Wytwórcy Manufacturer code	77174		
Nr korekty Proof No	1	Data Date	27.11.2019		
Kod wersji Valeant version code	P1UKIE03	Inny kod Other code	77174 (Data Matrix)		
Rozmiar czcionki Font size	minimum 8 pt	Wymiar ulotki PIL size	160 x 240 mm		
Krój czcionki Font used	Frutiger Neue LT W1G Condensed Frutiger Neue LT W1G Condensed Bold	Gramatura papieru Paper weight	60 g/m <sup>2</sup>		
Komentarze Comments (Reason for the change)					
<b>creating a shared pack for UK and Ireland</b> <b>PMR_ICN-19-1132-A</b> <b>Packing Site: Laboratoire Chauvin / Bausch &amp; Lomb</b>					
Akceptacja Techniczna Technical Approval					
					
Akceptacja Działu ds. Rejestracji Regulatory Affairs Dept. Approval					
					

#### 4. Possible side effects

The following side effects may occur occasionally:

- the skin around the eyes can be sore. Your eyes can be swollen, red and itchy. This is more likely to happen if the drops are used more than once.
- dry mouth,
- flushing of the skin,
- increased body temperature,
- constipation,
- difficulty in passing urine,
- fast heartbeat.

#### Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet. You can also report side effects directly via:

UK: Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

Ireland: HPRa Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971; Fax: +353 1 6762517, Website: [www.hpra.ie](http://www.hpra.ie); e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

Malta: [www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal).

By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. How to store your eye drops

Keep out of the sight and reach of children.

Do not use the eye drops after the expiry date which is stated on the overwrap of each unit and on the carton after the letters "EXP". The expiry date refers to the last day of that month.

Do not store above 25°C. Do not freeze. Store in original package in order to protect from light.

The drops are for single use only and provided in single use Minims units, to treat both eyes if necessary. Once opened, use immediately. Discard any unused portion.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

#### 6. Further information

##### What do your eye drops contain

- The active ingredient is atropine sulphate. Each Minims unit contains approximately 0.5 ml eye drops solution of atropine sulphate 1% w/v (5 mg).
- The other ingredients are hydrochloric acid (for pH adjustment) and purified water.

This medicine does not contain a preservative as it is a sterile single use unit.

##### Contents of the pack

Each carton contains 20 units.

##### Marketing Authorisation Holder (UK):

Bausch & Lomb UK LTD,  
106 London Road,  
Kingston-Upon-Thames,  
Surrey, KT2 6TN,  
United Kingdom

##### Marketing Authorisation Holder (Ireland and Malta):

Bausch Health Ireland Limited  
3013 Lake Drive Citywest Business Campus,  
Dublin 24,  
Ireland

##### Manufacturer:

Laboratoire Chauvin - Z.I.Ripotier - 07200 Aubenas - France

##### Marketing Authorisation Numbers:

Minims® Atropine Sulphate 1% w/v:  
PL03468/0068 (UK); MA1302/00301 (Malta); PA22698/001/001 (Ireland)

**DATE OF PREPARATION:** November 2019

Minims is a trademark of Bausch & Lomb Incorporated or its affiliates.

©2019 Bausch & Lomb Incorporated or its affiliates.