



Graphics&Packing Technology Section ICN POLFA RZESZÓW S.A.		<b>ULOTKA PIL</b>		<b>BAUSCH + LOMB</b>	
Nazwa produktu Product Name		Minims Chloramphenicol 0.5% w/v DRP		Kolor nadruku Colours	
				Black	
Kraj Country (ISO)		United Kingdom (UK), Ireland (IE)		Nr wykrojnika Spec No	
				5338	
Opracowane przez Designed by				Kod Wytwórcy Manufacturer code	
				76836	
Nr korekty Proof No		10		Kod farmaceutyczny Pharmacode	
Data Date		30.04.2015		-	
Kod wersji Valeant version code		P1UK01		Inny kod Other code	
				76836 (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	
				- g/m <sup>2</sup>	
Komentarze Comments (Reason for the change)					
MAH transfer from Chauvin Pharmaceuticals Ltd UK to B+L UK Ltd PMR_ICN-14-0678-A Packing Site: Aubenas Plant					
Akceptacja Techniczna Technical Approval					
Akceptacja Działu ds. Rejestracji Regulatory Affairs Dept. Approval					

**Bausch & Lomb**

## Minims® Chloramphenicol 0.5%

### Eye Drops, solution Chloramphenicol

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® Chloramphenicol 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® Chloramphenicol eye drops are and what are they used for

Minims® Chloramphenicol contains an antibiotic. It is used to treat infections of your eyes.

Sometimes parts of the outer surface of the eye, such as the cornea (the transparent membrane covering the surface of the eye) or the conjunctiva (the lining of the inside of the eyelids and part of the eye), may become infected with bacteria. These eye drops can be used to treat this infection and are effective against many different types of bacteria.

If the eye infection is very severe, your doctor may give you antibiotic tablets as well as this antibiotic eye drops. 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 (chloramphenicol) or any of the ingredients (refer to the end of this leaflet).

**Take special care**

If you use these eye drops over a long period of time they could possibly become less effective or produce allergic reactions. In order to prevent this, make sure that you stop using this medicine as soon as your doctor tells you to.

**Do you use any of these medicines?**

Chymotrypsin (solution used during cataract surgery) may not work properly when used at the same time as Minims® Chloramphenicol. 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 throughout the entire treatment course.

**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

**Do not use this product for longer than the time frame stated by your doctor or eye specialist, as it may become less effective at treating your eye infection.**

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

**Dosage**

The normal dose is 1 to 2 drops to each infected eye up to six times a day.

If you have a severe infection your doctor or eye specialist may ask you to use this medicine more frequently at first, until the infection starts to get better. The frequency of treatment can then be gradually reduced.

**If your eyes get worse** or are not better after a few days of using these eye drops, see your doctor or eye specialist or pharmacist.

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Art.76836  
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#### Method of administration

Make sure you 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 or 2 drops inside your lower eyelid.  
Make sure the dropper does not touch any parts of your eye.
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® Chloramphenicol 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. If you forget to use Minims® Chloramphenicol, you should take the missed dose as soon as you remember, unless it is nearly time for the next dose, but you should not take a double dose to make up for a missed dose.

#### 4. Possible side effects

- Minims® Chloramphenicol may cause burning, stinging, itching and skin irritation (including dermatitis) around the area it has been used on. These effects are not permanent.
- Aplastic anaemia (condition in which the bone marrow is unable to produce blood cells) and bone marrow depression can occur but these are extremely rare and your doctor will have taken your medical history into account when deciding to prescribe Minims® Chloramphenicol. Pale skin, weakness, increased heart rate, out of breath, headache, pain, fever, infection, bruises may be a sign a severe blood disorder.

If any of the side effects gets serious, please seek immediate medical attention. If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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

Keep out of the reach and sight 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.

Store in a refrigerator (2°C - 8°C). Do not freeze. Store in the original package in order to protect from light.

If necessary, the product may be stored at temperature not exceeding 25°C for up to 1 month only and then thrown away.

In that case, affix a label bearing the relevant expiry date to the carton label.

The drops are for single use only and provided in single use Minims units, to treat both eyes if both eyes are infected. 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 chloramphenicol. Each Minims unit contains approximately 0.5 ml eye drops solution of chloramphenicol 0.5% w/v (2.5 mg).
- The other ingredients are borax, boric acid 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:

Bausch & Lomb UK Ltd.  
106 London Road - Kingston-upon-Thames - KT2 6TN - UK  
Tel: +44 (0)20 8781 2900 / Fax: +44 (0)20 8781 2901

##### Manufacturer:

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

##### Marketing Authorisation Numbers:

Minims® Chloramphenicol 0.5% w/v :  
PL 03468/0069 (UK); PA 555/13/1 (Ireland)

**DATE OF PREPARATION:** April 2015

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