



Graphics&Packing Technology Section ICN POLFA RZESZÓW S.A.		ULOTKA PIL		<b>BAUSCH + LOMB</b>	
Nazwa produktu Product Name	<b>Minims Tetracaine Hydrochloride 0,5% and 1% w/v DRP SOL</b>		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	76863	
Nr korekty Proof No	6	Data Date	09.04.2015	Kod farmaceutyczny Pharmacode	-
Kod wersji Valeant version code	P9UKIE01		Inny kod Other code	76863 (Data Matrix)	
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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-14-0811-A Packing Site: Laboratoire Chauvin, Aubenas, France					
Akceptacja Techniczna Technical Approval					
Akceptacja Działu ds. Rejestracji Regulatory Affairs Dept. Approval					

## Minims® Tetracaine Hydrochloride 0.5% w/v Minims® Tetracaine Hydrochloride 1% w/v Eye Drops, solution Tetracaine Hydrochloride

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® Tetracaine Hydrochloride 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® Tetracaine Hydrochloride eye drops are and what are they used for

Minims® Tetracaine Hydrochloride contains a local anaesthetic. It is used to numb the eye temporarily. Your doctor or eye specialist may use it to examine or treat your eye without it being painful.

This medicine should be avoided in premature babies.

### 2. Before you use your eye drops

#### Do not use these drops if

- if you are allergic to the active substance (tetracaine) or any of the other ingredients (refer to the end of this leaflet).
- if you are allergic to other similar types of local anaesthetic.
- if you are taking medicines used to treat bacterial infection or diabetes called "sulphonamides".
- in premature babies.

#### Take special care

Your eye drops are not intended for long term use. Frequent use of local anaesthetic in the eye over long periods of time may severely affect your eyesight.

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

- medicines called "sulphonamides" used to treat bacterial infection or diabetes.

If the answer to any of these questions is yes, tell your doctor or eye specialist.

#### 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. There is no information on the effect of this product on contact lenses. Therefore, 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

A doctor or eye specialist will use these eye drops to examine your eye.

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

#### Dosage

The usual dose is 1 drop of solution in one or both eyes.

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 put the drops in your eye for you.

He/she may ask you 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.

He/she will then throw away the Minims unit, even if some solution remains.

Your eye will remain numb, depending on how many drops you received. Avoid touching the eye until the anaesthetic has worn off.

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Your doctor or eye specialist will make sure that your eye is properly protected.

**If you use more Minims® Tetracaine Hydrochloride 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.

#### 4. Possible side effects

Minims® Tetracaine may sting or burn when the drops are first put in and your vision may become blurred. This will gradually wear off.

Occasionally, the skin around the eyes can become sore, superficial defect or swelling of cornea (the transparent membrane covering the surface of the eye) may also be observed after short-term application of these eye-drops. If you find that you have itching, discomfort, soreness around your eyes or blurred vision that is causing you a problem, you should tell your doctor or pharmacist.

The cornea (the transparent membrane covering the surface of the eye) may be damaged by prolonged administration of anaesthetic eye drops.

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.

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

The drops are for single use only and provided in single use Minims units, to examine 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 tetracaine hydrochloride. Each unit contains approximately 0.5 ml eye drops solution of tetracaine hydrochloride 0.5% w/v (2.5 mg) or 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:

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##### Manufacturer:

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

##### Marketing Authorisation Numbers:

Minims® Tetracaine Hydrochloride 0.5% w/v:

PL 03468/0082 (UK) ; PA 555/21/1 (Ireland)

Minims® Tetracaine Hydrochloride 1% w/v:

PL 03468/0083 (UK) ; PA 555/21/2 (Ireland)

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