

Graphics&Packing Technology Section ICN POLFA RZESZÓW S.A.				ULOTKA PIL		BAUSCH + LOMB	
Nazwa produktu Product Name		Minims Artificial Tears 0.35% w/w & 0.44% w/w DRP SOL		Kolor nadruku Colours			
				Black			
Kraj Country (ISO)		United Kingdom (UK), Ireland (IE)		Nr wykrojnika Spec No		5338_F	
Opracowane przez Designed by		5537		Kod Wytwórcy Manufacturer code		77114	
Nr korekty Proof No		2		Data Date		07.03.2019	
Kod wersji Valeant version code		P1UKIE04		Inny kod Other code		-	
Rozmiar czcionki Font size		minimum 9 pt		Wymiar ulotki PIL size		160 x 240 mm	
Krój czcionki Font used		Baush&Lomb Bold Baush&Lomb Regular		Gramatura papieru Paper weight		60 g/m ²	
Komentarze Comments (Reason for the change)							
Brexite PMR_ICN-19-0185-A Packing Site: Laboratoire Chauvin, Aubenas, France							
Akceptacja Techniczna Technical Approval							
<div style="border: 1px dashed black; width: 90%; margin: 0 auto; height: 100px;"></div>							
Akceptacja Działu ds. Rejestracji Regulatory Affairs Dept. Approval							
<div style="border: 1px dashed black; width: 90%; margin: 0 auto; height: 100px;"></div>							

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Minims® Artificial Tears

0.35% w/w Sodium Chloride + 0.44%w/w Hyetellose Eye Drops, Solution

Read all of this leaflet carefully before you start using this medicine because it contains important information for you. Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet:

1. What Minims® Artificial Tears eye drops is and what it is used for
2. What you need to know 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. Contents of the pack and other information

1. What Minims® Artificial Tears eye drops is and what it is used for

Minims® Artificial Tears contains a lubricant. It is used as a substitute for natural tears. This medicine is indicated for children, adults and the elderly.

2. What you need to know before you use your eye drops

There are no special precautions which should be taken before using this product.

Pregnancy, breast-feeding and fertility

You can use Minims® Artificial Tears as it will not harm your baby, and it is safe to use during breastfeeding.

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 in special single use "Minims" units, to treat both eyes if necessary. Once used, they must be thrown away.

Dosage

The amount of solution used should be enough to irrigate the eye properly.

Method of administration

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. Twist and pull cap to separate from the Minims body (Diagram 1).
4. Pull your lower eyelid down gently, and then gently squeeze until some liquid falls inside your lower eyelid.
Make sure the dropper does not touch any parts of your eye.
5. Close the eyelids.
6. Repeat steps 4 and 5 for the other eye, then throw away the Minims unit even if some solution remains.

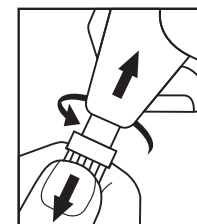


Diagram 1

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Opracowane przez Designed by	5537		Kod Wytwórcy Manufacturer code	77114	
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					77114 Data Matrix
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4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. You may briefly have blurred vision or a slight stinging feeling after using your drops.

Reporting of side effects

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

Ireland

Hpra Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

United Kingdom

Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard

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

5. How to store your eye drops

Keep this medicine out of the sight and reach of children.

Do not use this medicine 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 to protect from light.

The drops are in special single use "Minims" units, to treat both eyes if necessary. Once used, they must be thrown away.

6. Contents of the pack and other information

What your eye drops contain

- The active ingredients are hyetellose and sodium chloride. Each Minims unit contains approximately 0.5 ml eye drops solution of hyetellose 0.44% (2.2 mg) and sodium chloride 0.35% (1.75 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.

One of the active ingredients in this medicine is hyetellose. This is the new name for hydroxyethylcellulose. The ingredient itself has not changed.

What your eye drops look like and contents of the pack

It is a clear, colourless solution.

Each carton contains 20 units.

Marketing Authorisation Holder:

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3013 Lake Drive,
Citywest Business Campus,
Dublin 24 Ireland

Manufacturer:

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

A copy of this Patient Information Leaflet is available in large print and audio format at www.xpil.medicines.org.uk

This leaflet was last revised in: March 2019