



Graphics&Packing Technology Section ICN POLFA RZESZÓW S.A.		ULOTKA PIL		BAUSCH + LOMB	
Nazwa produktu Product Name	Minims fluorescein sodium 1% and 2% DRP SOL		Kolor nadruku Colours		
			Black		
Kraj Country (ISO)	UK; IE		Nr wykrojnika Spec No	5338 revision F	
Opracowane przez Designed by	Łukasz Koziol lukasz.kozioł@valeant.com Phone: +48 17 865 5537		Kod Wytwórcy Manufacturer code	77104	
Nr korekty Proof No	2	Data Date	12.03.2019	Kod farmaceutyczny Pharmacode	-
Kod wersji Valeant version code	P9UK02		Inny kod Other code	77104 (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	60 g/m ²	
Komentarze Comments (Reason for the change)					
Brexit PMR_ICN-19-0137-A Packing Site: Laboratoire Chauvin Aubenas					
Akceptacja Techniczna Technical Approval					
Akceptacja Działu ds. Rejestracji Regulatory Affairs Dept. Approval					

Minims® Fluorescein Sodium 1% w/v

Minims® Fluorescein Sodium 2% w/v

Eye Drops, solution
Fluorescein sodium

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® Fluorescein sodium 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® Fluorescein sodium eye drops are and what they are used for

Minims® Fluorescein sodium contains a diagnostic agent. The active substance, fluorescein sodium, is a temporary dye used to:

- help your doctor or eye specialist to examine your eye,
- help your doctor or eye specialist to measure the pressure inside your eye by a test called tonometry,
- help in the fitting of hard contact lenses.

Scratches on the conjunctiva (the lining of the inside of the eyelids and part of the eye) are stained yellow or orange by fluorescein.

Damages to the cornea (the transparent membrane covering the surface of the eye) are stained green.

Any foreign bodies which are stuck in your eye are surrounded by a green ring.

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 (fluorescein).
- you wear soft contact lenses.

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 soft contact lenses prior to the administration of the drops. There is no information on the effect of this product on soft contact lenses. Therefore, do not wear your soft 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. This will wear off within a few minutes. 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 normal dose is 1 to 2 drops in one or both eyes.

Enough solution should be used to make sure that any damaged areas are stained.

Method of administration

The doctor or eye specialist will put the drops in your eye for you.

A sterile eyewash may be used to wash away any excess solution.

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4. Possible side effects

The following side-effects have been reported very rarely:

- allergic reactions with redness and irritation of the eye, swelling around the eye,
- severe allergic reaction with difficulty in breathing and symptoms of shock,
- itchy skin rash with raised red blotches.

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 fluorescein sodium. Each unit contains approximately 0.5 ml eye drops solution of fluorescein sodium 1% w/v (5 mg) or 2% w/v (10 mg).
- The other ingredient is 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 Holders:

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Manufacturer:

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Marketing Authorisation Number:

Minims® Fluorescein sodium 1% w/v :

PL 03468/0073 (UK) ; PA22698/008/001 (Ireland)

Minims® Fluorescein sodium 2% w/v :

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