1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S1

MINIMS® FLUORESCEIN SODIUM 2 %

Eye drops, solution in single-dose container

Read all of this leaflet carefully because it contains important information for you

MINIMS® Fluorescein eye drops are available without a doctor's prescription; however, it will be administered by a person who is qualified to do so, such as your doctor.

- Keep this leaflet. You may need to read it again.
- Do not share MINIMS® Fluorescein eye drops with any other person.
- Ask your pharmacist if you need more information or advice.

What is in this leaflet

1. What MINIMS® Fluorescein is and what it is used for
2. What you need to know before you use MINIMS® Fluorescein
3. How to use MINIMS® Fluorescein
4. Possible side effects
5. How to store MINIMS® Fluorescein
6. Contents of the pack and other information

1. What MINIMS® Fluorescein is and what it is used for

Minims® Fluorescein eye drops contain 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.

2. What you need to know before you use MINIMS® Fluorescein eye drops

MINIMS® Fluorescein eye drops should not be administered to you:

- if you are hypersensitive (allergic) to fluorescein or any of the other ingredients of MINIMS® Fluorescein eye drops (listed in section 6).
- if you wear soft contact lenses.

Warnings and precautions

Special care should be taken with MINIMS® Fluorescein eye drops:

Contact lenses:

Tell your doctor if you wear soft 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.

Each MINIMS® unit should be discarded after a single use to prevent microbial contamination.

Other medicines and MINIMS® Fluorescein eye drops:

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

Pregnancy and breastfeeding:

Safety for use in pregnancy and lactation has not been established.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before being administered MINIMS® Fluorescein eye drops.
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using this medicine.

Driving and using machines:

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 MINIMS® Fluorescein

Do not share medicines prescribed for you with any other person.
You will not be expected to administer MINIMS® Fluorescein eye drops yourself. It will be administered by a person who is qualified to do so.
A doctor or eye specialist will use these eye drops to examine your eye.
The drops are in special single use MINIMS® units, to examine both eyes if necessary. Once opened, the eye drops must be used immediately. Discard any unused portion.

Dosage

The normal dose is 1 to 2 drops in one or both eyes.

Method of administration

The doctor or eye specialist will put the drops in your eye for you. Sterile eyewash may be used to wash away any excess solution.

If you are given more MINIMS® Fluorescein than you should:

Since a healthcare professional will administer MINIMS® Fluorescein eye drops, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

4. Possible side effects

MINIMS® Fluorescein can have side effects. Not all side effects reported for MINIMS® Fluorescein are included in this leaflet. Should your general health worsen or if you experience any untoward effects while MINIMS® Fluorescein eye drops are being administered, please consult your doctor, pharmacist or other health care professional for advice.

The following side effects have been reported less frequently:

- 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 you notice any other effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to Holder of the Certificate of registration using the following e-mail address: PV-SouthAfrica@bauschhealth.com, or directly to SAHPRA using an ADR reporting form or the e-reporting portal available on SAHPRA'S website: https://www.sahpra.org.za/health-products-vigilance/

By reporting side effects, you can help provide more information on the safety of MINIMS® Fluorescein.

5. How to store MINIMS® Fluorescein

Store all medicines out of reach of children.

- Store in the refrigerator at 2-8 °C.
- Protect from light. Do not freeze.

- Keep the units in the outer container until required for use.
- Do not use the eye drops after the expiry date printed on the container.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What MINIMS® Fluorescein contains

- The active substance is fluorescein sodium. Each dispensing unit of 0,5 ml contains 10 mg of fluorescein sodium (2 % *m/v*)
- The other ingredient is purified water

What MINIMS® Fluorescein looks like and contents of the pack

MINIMS® Fluorescein is an eye drops solution in a single-dose container.

The eye drops are a clear, orange red solution, reasonably free from visible particulate matter.

MINIMS® Fluorescein eye drops are provided in a sealed conical shaped polypropylene container fitted with a twist and pull-off cap. Each unit contains approximately 0,5 ml of solution. Each unit is individually overwrapped in a polypropylene/paper sachet. The sachets are packed in cartons of 20 units.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

The Professional Information is available on the company website, www.bausch.co.za, or may be requested telephonically: +27 10 025 2100.