

PROFESSIONAL INFORMATION

SCHEDULING STATUS

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1 NAME OF THE MEDICINE

MINIMS[®] FLUORESCEIN SODIUM 2 %

Eye drops, solution in single-dose container

2 QUALITATIVE AND QUANTITATIVE

Sterile preservative-free solution containing 10 mg fluorescein sodium per dispensing unit of 0,5 ml (2,0 % *m/v*) as the active ingredient.

For full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution in single-dose container.

A clear, orange red solution, reasonably free from visible particulate matter.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For use in detecting corneal abrasions and foreign bodies in the eye, in applanation tonometry, in assessing the patency of the nasolacrimal duct and in contact lens fitting procedures.

4.2 Posology and method of administration

Instil dropwise into the eye.

Sufficient solution should be applied to stain the damaged areas. Excess may be washed away with sterile saline solution.

Each MINIMS[®] unit should be discarded after use.

4.3 Contraindications

Hypersensitivity to fluorescein sodium, or any other ingredients (see **6.1 List of excipients**).

Not to be used with soft contact lenses.

4.4 Special warnings and precautions for use

Special care should be taken to avoid microbial contamination. *Pseudomonas aeruginosa* grows well in fluorescein solutions, therefore, a single dose solution is preferred.

Each MINIMS[®] unit should be discarded after a single use.

4.5 Interaction with other medicines and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

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

4.7 Effects on ability to drive and use machines

May cause transient blurring of vision on instillation. Patients should be warned not to drive or operate hazardous machinery until vision is clear.

4.8 Undesirable effects

Symptoms of allergic-type reactions and anaphylaxis have been reported following topical ophthalmic administration of MINIMS[®] Fluorescein eye drops and may manifest as:

Immune system disorders:

Less frequent: anaphylactic reaction

Eye disorders:

Less frequent: allergic conjunctivitis, periorbital oedema

Skin and subcutaneous tissue disorders:

Less frequent: urticaria, rash, angioedema

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit-risk of the medicine. Health care providers are asked to report any suspected adverse reactions to the 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/>

4.9 Overdose

Overdose following the recommended use is unlikely. Treatment is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 15.4 Ophthalmic preparations: Other

Fluorescein acts as a diagnostic stain. It stains corneal and conjunctival abrasions or ulcers a bright green, and foreign bodies are surrounded by a green ring. Loss of substance in the conjunctiva is indicated by a yellow stain.

5.2 Pharmacokinetic properties

Fluorescein will resist penetration of a normal cornea and most excess solution will, therefore, be carried with the tear film away from the conjunctival sac.

The majority will be lost through the naso-lacrimal ducts and absorbed via the gastro-intestinal tract from where it is converted rapidly to its glucuronide and excreted via the urine.

If fluorescein crosses the cornea it will enter the Bowman's membrane, stroma and possibly the anterior chamber. Aqueous flow and diffusion into the blood in the anterior chamber finally removes fluorescein from the eye and it is excreted unchanged in the urine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified water

6.3 Shelf life

30 months

6.4 Special precautions for storage

Store in the refrigerator between 2-8 °C. Protect from light.

DO NOT FREEZE.

Keep the units in the outer container until required for use.

6.5 Nature and contents of container

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.

6.6 Special precautions for disposal

Each MINIMS[®] unit should be discarded after single use.

7 HOLDER OF CERTIFICATE OF REGISTRATION

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8 REGISTRATION NUMBER

T/15.4/86

9 DATE OF FIRST AUTHORISATION

28 February 1986

10 DATE OF REVISION OF THE TEXT

13 August 2020