Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Minims Fluorescein Sodium 2%, w/v Eye Drops, Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

2% w/v solution of Fluorescein Sodium

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Eye Drops, solution (Eye Drops)
Clear, orange-red, aqueous single-use eye drop solution

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As a diagnostic stain.

Fluorescein does not stain a normal cornea but conjunctival abrasions are stained yellow or orange, corneal abrasions or ulcers are stained a bright green and foreign bodies are surrounded by a green ring.

Fluorescein can be used in diagnostic examinations including Goldmann tonometry and in the fitting of hard contact lenses.

4.2 Posology and method of administration

Adults, Children and the Elderly

Instil dropwise into the eye.

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

4.3 Contraindications

Use in patients with a known hypersensitivity to Fluorescein.

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.
Each Minims unit should be discarded after a single use.

4.5 Interaction with other medicinal products and other forms of interactions

None known.

4.6 Fertility, pregnancy and lactation

Safety for use in pregnancy and lactation has not been established, therefore use only when considered essential by the physician.

4.7 Effects on ability to drive and use machines

May cause transient blurring of vision on instillation. Warn patients not to drive or operate hazardous machinery until vision is clear.

4.8 Undesirable effects

ADRs are very rare (<1/10,000), including isolated reports.

Symptoms of allergic-type reactions and anaphylaxis have been reported following topical ophthalmic administration of Fluorescein sodium and may manifest as:

Eye disorders: allergic conjunctivitis, peri-orbital oedema

Immune system disorders: anaphylactic reaction

Skin and subcutaneous tissue disorders: urticaria, rash

4.9 Overdose

Overdose following the recommended use is unlikely.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Fluorescein acts as a diagnostic stain.

5.2 Pharmacokinetic properties

Fluorescein will resist penetration of a normal cornea and most excess solution will, therefore, be carried out 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.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of this SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified Water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened: 15 months.
Once opened: Each Minims unit should be used immediately, discard any unused portion.

6.4 Special precautions for storage

Store below 25°C. Do not freeze. Store in the original container in order to protect from light.

6.5 Nature and contents of container

A sealed conical shaped polypropylene container fitted with a twist and pull off cap made from Ph. Eur. grade polypropylene for containers and closures for parenteral and ophthalmic preparations. Each Minims unit contains approximately 0.5ml of solution. Each unit is overwrapped in a polypropylene/paper pouch. 20 units are packed into a suitable carton.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Each Minims unit should be discarded after use.

7 MARKETING AUTHORISATION HOLDER

Bausch + Lomb Ireland Limited
3013 Lake Drive
Citywest Business Campus
Dublin 24
D24 PPT3
Ireland

8 MARKETING AUTHORISATION NUMBER

PA23259/012/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1983

Date of last renewal: 01 April 2008

10 DATE OF REVISION OF THE TEXT

June 2022