

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1 NAME OF THE MEDICINAL PRODUCT**

Minims Fluorescein Sodium 1%

### **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

1% w/v solution of Fluorescein Sodium BP.

### **3 PHARMACEUTICAL FORM**

Single-use, sterile eye drops.

### **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**

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 medicinal products and other forms of interaction**

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 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**

None known.

### **6.3 Shelf life**

Unopened: 15 months.

### **6.4 Special precautions for storage**

Store below 25°C. Do not freeze. Protect from light.

### **6.5 Nature and contents of container**

A sealed conical shaped polypropylene container fitted with a twist and pull off cap. 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**

Each Minims unit should be discarded after use.

**7      MARKETING AUTHORISATION HOLDER**

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**8      MARKETING AUTHORISATION NUMBER(S)**

PL 03468/0073

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22/11/2001

**10     DATE OF REVISION OF THE TEXT**

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