

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Minims Lidocaine & Fluorescein.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Clear, slightly yellow, slightly viscous eye drops containing Lidocaine Hydrochloride Ph.Eur 4% w/v and Fluorescein Sodium BP 0.25% w/v.

3 PHARMACEUTICAL FORM

Single-use, sterile eye drops.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

As a diagnostic stain and topical anaesthetic combined. Minims Lidocaine & Fluorescein can be used in the measurement of intraocular pressure by Goldmann tonometry.

4.2 Posology and method of administration

Adults (including the elderly):

One or more drops, as required.

Children:

As directed by the physician.

4.3 Contraindications

Do not use in patients with a known hypersensitivity to fluorescein or Lidocaine and other amide-type local anaesthetics.

4.4 Special warnings and precautions for use

The anaesthetised eye should be protected from foreign body contamination, particularly in elderly patients in whom the duration of anaesthesia may exceed 30 minutes.

Use with caution in an inflamed eye as hyperaemia greatly increases the rate of systemic absorption through the conjunctiva.

Systemic absorption may be reduced by compressing the lacrimal sac at the medial canthus for a minute during and following the instillation of the drops. (This blocks the passage of the drops via the naso-lacrimal duct to the wide absorptive area of the nasal and pharyngeal mucosa. It is especially advisable in children.)

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, Pregnancy and lactation

This combination has been used for a number of years without apparent ill-consequence.

4.7 Effects on ability to drive and use machines

None known.

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 is not expected to cause any adverse effects, however, overuse of local anaesthetics can cause keratitis, with loss of corneal epithelium and stromal opacity.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Lidocaine is an established topical anaesthetic which blocks the sensory nerve endings of the cornea.

The fluorescein moiety 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.

5.2 Pharmacokinetic properties

None relevant.

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 the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polyvidone
Hydrochloric Acid
Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf life

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 container fitted with a twist and pull-off cap. Each Minims unit is overwrapped in an individual polypropylene/paper pouch. Each container holds approximately 0.5ml of solution.

6.6 Special precautions for disposal

Each Minims unit should be discarded after a single use.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

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