Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Minims Lidocaine Hydrochloride 4% w/v & Fluorescein Sodium 0.25% w/v Eye Drops, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Lidocaine Hydrochloride 4 % w/v and Fluorescein Sodium 0.25 % w/v

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Eye drops, solution (eye drops)
Single use, sterile, clear, slightly yellow, slightly viscous eye drops, solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As a diagnostic stain and local 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 to two drops, as required.

Children:
As directed by the physician.

4.3 Contraindications

Do not use in patients with a known hypersensitivity to either of the active ingredients.

4.4 Special warnings and precautions for use

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

The cornea may be damaged by prolonged application of anaesthetic eye drops.

The anaesthetised eye should be protected from dust and contamination.

Systemic absorption may be minimised by compressing the lacrimal sac at the medial canthus for one minute during and after 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 interactions

None known.

4.6 Fertility, pregnancy and lactation

None known.

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

None known.

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

Povidone
Hydrochloric Acid (for pH adjustment)
Purified Water

6.2 Incompatibilities

In the absence of compatibility studies this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

Unopened: 15 months
Once opened: use immediately, discard any unused portion.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

A sealed conical shaped 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 is over wrapped in an individual polypropylene/paper pouch. Each container holds approximately 0.5 ml of solution. There are 20 Minims units in every 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 a single use.

7 MARKETING AUTHORISATION HOLDER

Bausch + Lomb Ireland Limited
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Dublin 24
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8 MARKETING AUTHORISATION NUMBER

PA23259/014/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last authorisation: 24 March 2008

10 DATE OF REVISION OF THE TEXT

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