NEW ZEALAND DATA SHEET

1 MINIMS Lidocaine & Fluorescein, eye drops solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.5 mL contains 20 mg lidocaine hydrochloride monohydrate and 1.25 mg of fluorescein sodium.

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Clear, slightly-yellow, slightly viscous, 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 Dose 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 medicaments 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 conjunctivits, peri-orbital oedema
Immune system disorders: anaphylactic reaction
Skin and subcutaneous tissue disorders: urticaria, rash

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting/

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.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

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 data sheet.

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6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polyvinyl Pyrrolidone
Hydrochloric Acid
Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf Life

30 months.

6.4 Special precautions for storage

Store at 2°-8°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 MEDICINE SCHEDULE

Prescription medicine

8 SPONSOR

Bausch & Lomb (NZ) Ltd c/-
Bell Gully
Auckland Vero Centre 48
Shortland Street
Auckland 1140
New Zealand

9 DATE OF FIRST APPROVAL

14 June 1978.

10 DATE OF REVISION OF THE TEXT

29 May 2024

NEW ZEALAND DATA SHEET

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
2	Minor changes to active ingredient names