AUSTRALIAN PRODUCT INFORMATION – MINIMS® LIDOCAINE AND FLUORESCEIN [LIDOCAINE HYDROCHLORIDE MONOHYDRATE AND FLUORESCEIN SODIUM] EYE DROPS

1 NAME OF THE MEDICINE

Lidocaine Hydrochloride Monohydrate and Fluorescein Sodium

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Minims Lidocaine and Fluorescein Eye Drops contain lidocaine hydrochloride monohydrate 4% w/v and fluorescein sodium 0.25% w/v. No preservatives are contained in the formulation.

For the full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

A single-use eye drops, solution.

Minims Lidocaine and Fluorescein Eye Drops are clear, fluorescent red-orange sterile eye drops. No preservatives are contained in the formulation.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

As a diagnostic stain and topical anaesthetic combined, Minims Lidocaine and Fluorescein is intended primarily to facilitate Goldmann applanation tonometry.

4.2 DOSE AND METHOD OF ADMINISTRATION

Adults (including the elderly)
One or more drops as required.

Children
One or more drops as required or as directed by the physician.

Systemic absorption of lidocaine and fluorescein 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.)

Each Minims Lidocaine and Fluorescein Eye Drops unit should be discarded after a single use.

4.3 CONTRAINDICATIONS

Minims Lidocaine and Fluorescein Eye Drops are contraindicated in patients with hypersensitivity to any of the components of the preparation or other amide-type local anaesthetics.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Identified precautions

Minims Lidocaine and Fluorescein Eye Drops are for topical ophthalmic application only. The solution should not be injected.

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

Patients should be warned not to touch or rub the eye while anaesthesia persists. The anaesthetised eye should be protected from dust and bacterial contamination

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

Prolonged use of topical anaesthetics in the eye can lead to severe chemical keratitis.

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Use in the elderly

A second drop may be needed to obtain the anaesthetic effect.

Paediatric use

Minims Lidocaine and Fluorescein Eye Drops should be used with caution in children.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

No interaction studies have been performed.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

Studies have not been performed in either animals or humans to evaluate the potential fertility impairing effects of lidocaine and fluorescein, either alone or in combination.

Use in pregnancy – Pregnancy Category A

No animal or well-controlled human studies have been conducted with lidocaine and fluorescein in combination to evaluate the potential effects on embryofoetal development.

Lidocaine readily crosses the placenta. However, no foetal harm was observed in animal studies with either of the single agents, and this combination has been used for a number of years without apparent ill consequences.

Use in lactation.

Lidocaine and fluorescein are excreted in breast milk. However, this combination has been used for a number of years without apparent ill consequences.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Minims Lidocaine and Fluorescein Eye Drops may cause stinging and transient blurring of vision. Patients should be advised not to drive or operate hazardous machinery until vision is clear.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

Adverse reactions associated with topical fluorescein and anaesthetic-fluorescein combination are usually limited to transient irritation of the cornea or conjunctiva.

4.9 OVERDOSE

For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia).

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

Mechanism of action

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

Fluorescein sodium is used as a diagnostic dye in ophthalmic procedures. It stains damaged cornea and ocular fluids and is applied to the eye for the detection of corneal lesions and foreign bodies, as an aid to the fitting of hard contact lenses, and in various other diagnostic ophthalmic procedures. Fluorescein does not stain a normal cornea. With slit lamp examination using a blue filler, corneal abrasions or ulcers are stained a bright green and foreign bodies may be surrounded by a green ring.

Clinical trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

No data available.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

Studies have not been performed in either animals or humans to evaluate the potential, genotoxic effects of lidocaine and fluorescein, either alone or in combination. A metabolite of lidocaine, 2,6-xylidine, showed weak mutagenic and clastogenic activity in vitro, although it did not display genotoxicity in vivo.

Carcinogenicity

Studies have not been performed in either animals or humans to evaluate the potential carcinogenic effects of lidocaine and fluorescein, either alone or in combination. In a 2-year oral carcinogenic study in rats, the compound caused adenomas and carcinomas of the nasal cavity and subcutaneous fibromas and fibrosarcomas at a daily dose of 150 mg/kg. The carcinogenic potential of Minims Lidocaine and Fluorescein Eye Drops, used infrequently and at low doses, is likely to be low.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Povidone, hydrochloric acid and purified water.

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store at 2°C to 8°C. (Refrigerate. Do not freeze.). Do not expose to strong light.

6.5 NATURE AND CONTENTS OF CONTAINER

Minims Lidocaine and Fluorescein Eye Drops are supplied as a clear fluorescent red-orange coloured sterile eye drops in a single use polypropylene tube (unit) overwrapped in a polyester/paper blister. The blisters are packed in cartons of 20 units. Each unit contains approximately 0.5 mL solution.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

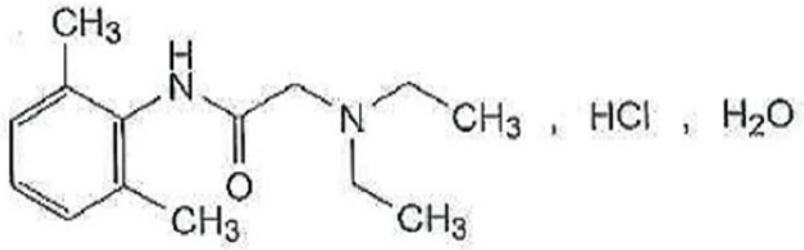
Each Minims Lidocaine and Fluorescein Eye Drops unit should be discarded after a single use.

In Australia, any unused medicine or waste material should be disposed of in accordance with local requirements.

6.7 PHYSICOCHEMICAL PROPERTIES

Lidocaine Hydrochloride Monohydrate

Chemical structure



Chemical name: 2-(Diethylamino)-N-(2,6-dimethylphenyl)acetamide hydrochloride monohydrate

Synonyms: Lignocaine hydrochloride

Molecular formula: $C_{14}H_{22}N_2O.HCl.H_2O$

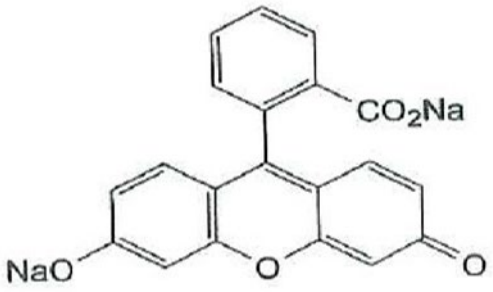
Molecular weight: 288.8

CAS number

6108-05-0

Fluorescein Sodium

Chemical structure



Chemical name: Disodium 2-(6-oxido-3-oxo-3H-xanthen-9-yl)benzoate

Molecular formula: $C_{20}H_{10}Na_2O_5$

Molecular weight: 376.3

CAS number

518-47-8

7 MEDICINE SCHEDULE (POISONS STANDARD)

S4 – Prescription Only Medicine

8 SPONSOR

Bausch & Lomb (Australia) Pty Ltd
Level 2, 12 Help Street
Chatswood, NSW 2067

9 DATE OF FIRST APPROVAL

27 May 2009

10 DATE OF REVISION

3 May 2024

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
All	Update active ingredient name from dual labelling to sole ingredient name