PRODUCT INFORMATION

MINIMS® LIGNOCAINE & FLUORESCIN EYE DROPS

NAME OF THE MEDICINE

Minims Lignocaine and Fluorescein Eye Drops contain the active ingredients lignocaine hydrochloride and fluorescein sodium.

**Lignocaine Hydrochloride**

Synonyms: Lidocaine hydrochloride

Structural formula:

![Chemical structure of Lignocaine Hydrochloride](image)

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

Molecular formula: C_{14}H_{22}N_{2}O.HCl.H_{2}O

Molecular weight: 288.8

CAS number: 6108-05-0

**Fluorescein Sodium**

Structural formula:

![Chemical structure of Fluorescein Sodium](image)

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

Molecular formula: C_{20}H_{10}Na_{2}O_{5}

Molecular weight: 376.3

CAS number: 518-47-8
DESCRIPTION
Minims Lignocaine and Fluorescein Eye Drops are clear, fluorescent red-orange sterile eye drops containing lignocaine hydrochloride 4% w/v and fluorescein sodium 0.25% w/v. The formulation also contains povidone, hydrochloric acid and purified water. No preservatives are contained in the formulation. Each unit contains approximately 0.5mL solution in a container that has a twist and pull cap. Each unit should be discarded after a single use. The solution has an acidic pH.

PHARMACOLOGY
Lignocaine 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.

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

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

PRECAUTIONS
Minims Lignocaine 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.

Systemic absorption of lignocaine 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.)

Use in pregnancy
No animal or well-controlled human studies have been conducted with lignocaine and fluorescein in combination to evaluate the potential effects on embryofoetal development. Lignocaine 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**
Lignocaine and fluorescein are excreted in breast milk. However, this combination has been used for a number of years without apparent ill consequences.

**Paediatric use**
Minims Lignocaine and Fluorescein Eye Drops should be used with caution in children.

**Use in the elderly**
A second drop may be needed to obtain the anaesthetic effect.

**Effects on fertility; carcinogenicity and genotoxicity**
Studies have not been performed in either animals or humans to evaluate the potential carcinogenic, genotoxic or fertility impairing effects of lignocaine and fluorescein, either alone or in combination. A metabolite of Lignocaine, 2,6-xyldine, showed weak mutagenic and clastogenic activity in vitro, although it did not display genotoxicity in vivo. 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 Lignocaine and Fluorescein Eye Drops, used infrequently and at low doses, is likely to be low.

**Effects on ability to drive and use machines**
Minims Lignocaine 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.

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

**DOSAGE AND 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 lignocaine 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 Lignocaine & Fluorescein Eye Drops unit should be discarded after a single use.
OVERDOSAGE
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.

PRESENTATION AND STORAGE CONDITIONS
Presentation: Minims Lignocaine & 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.

Storage conditions: Store at 2°C to 8°C. (Refrigerate. Do not freeze.). Do not expose to strong light.
Each Minims Lignocaine & Fluorescein Eye Drops unit should be discarded after a single use.

NAME AND ADDRESS OF THE SPONSOR
iNova Pharmaceuticals (Australia) Pty Ltd
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Chatswood, NSW 2067

POISION SCHEDULE OF THE MEDICINE
S4 – Prescription Only Medicine

DATE OF FIRST INCLUSION IN THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS (the ARTG)
27 May 2009

DATE OF MOST RECENT AMMENDMENT
16 September 2015