NEW ZEALAND DATA SHEET

1 MINIMS Oxybuprocaine Hydrochloride, eye drops solution 0.4% w/v

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.5 mL unit contains 2 mg Oxybuprocaine hydrochloride.
For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Clear, colourless, single-use, sterile eye drops.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

As a topical ocular anaesthetic.

4.2 Dose and method of administration

Adults (including the Elderly) and Children

One drop is sufficient when dropped into the conjunctival sac to anaesthetise the surface of the eye to allow tonometry after one minute. A further drop after 90 seconds provides adequate anaesthesia for the fitting of contact lenses. Three drops at 90 second intervals provide sufficient anaesthesia for a foreign body to be removed from the corneal epithelium or for incision of a meibomian cyst through the conjunctiva. Corneal sensitivity is normal again after about one hour.

Instil dropwise into the eye according to the recommended dosage.

Each Minims unit should be discarded after use.

4.3 Contraindications

Not to be used in patients with a known hypersensitivity to the product.

4.4 Special warnings and precautions for use

Transient stinging and blurring of vision may occur on instillation.

The anaesthetised eye should be protected from dust and bacterial contamination.

When applied to the conjunctiva, benoxinate is less irritant than amethocaine in normal concentrations.

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

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 stated.

4.6 Fertility, pregnancy and lactation

This product should not be used in pregnancy or lactation, unless considered essential by the physician.

4.7 Effects on ability to drive and use machines

Patients should be advised not to drive or operate hazardous machinery until normal vision is restored.

4.8 Undesirable effects

See Special warnings and special precautions for use.

In rare cases, local anaesthetic preparations have been associated with allergic reactions (in the most severe instances, anaphylactic shock).

Eye disorders:
Frequency unknown: eye allergy, allergic blepharitis.

Immune system disorder:
Frequency unknown: hypersensitivity, anaphylactic reaction/shock.

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 following the recommended use is unlikely.

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

Oxybuprocaine hydrochloride is used as a local anaesthetic as it reversibly blocks the propagation and conduction of nerve impulses along nerve axons.

5.2 Pharmacokinetic properties

The rate of loss of local anaesthetics through tearflow is very high as they induce an initial stinging reaction which stimulates reflex lacrimation and leads to dilution of the drugs. It is thought that this is responsible for the very short duration of maximum

effect of local anaesthetics. The non-ionised base of benoxinate is rapidly absorbed from the pre-corneal tear film by the lipophilic corneal epithelium. The drug then passes into the corneal stroma and from there into the anterior chamber where it is carried away by the aqueous flow and diffuses into the blood circulation in the anterior uvea. As with other ester type local anaesthetics, benoxinate is probably rapidly metabolised by plasma cholinesterases (and also by esterases in the liver).

5.3 Preclinical safety data

No adverse safety issues were detected during the development of this formulation. The active ingredient is well established in clinical ophthalmology.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydrochloric Acid
Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf life

Unopened: 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 polypropylene container fitted with a twist and pull off cap. Overwrapped in an individual polypropylene/paper pouch. Each container holds approximately 0.5ml of solution.

6.6 Special precautions for diposal

Each Minims unit should be discarded after 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

19 May 1987

10 DATE OF REVISION OF THE TEXT

19 February 2019

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
4.8	As a result of Signal Assessment report's recommendation this section was updated with the terms: "allergic reactions, eye allergy, blepharitis allergic, hypersensitivity, anaphylactic reaction/shock" with unknown frequency.