Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Minims Oxybuprocaine Hydrochloride 0.4% w/v Eye Drops Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Contains Oxybuprocaine Hydrochloride Ph. Eur. 0.4 % w/v.
Each unit (0.5ml) contains Oxybuprocaine Hydrochloride 2mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution
Clear, colourless, aqueous, sterile single use eye drop solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As a sterile, single use eye drop for use as an anaesthetic prior to tonometry, contact lens fitting, foreign body removal and meibomian cyst incision. The drops should be instilled topically into the conjunctival sac.

4.2 Posology and method of administration

Adults and Children:
One drop is sufficient to anaesthetise the surface of the eye to allow tonometry after one minute. A further drop after 90 seconds will provide adequate anaesthesia for the fitting of contact lenses. Three drops at 90 second intervals provides 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.

Each Minims unit should be discarded after use.

4.3 Contraindications

Known hypersensitivity to oxybuprocaine.

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.

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).

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

4.5 Interaction with other medicinal products and other forms of interactions

Oxybuprocaine is incompatible with chlorhexidine acetate. Avoid co-administration with other ophthalmic agents containing chlorhexidine acetate as a preservative.

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

The side effects are listed in the following frequencies:

Very common (≥ 1/10); Common (≥ 1/100, < 1/10); Uncommon (≥ 1/1,000, < 1/100); Rare (≥ 1/10,000, < 1/1,000); Very rare (< 1/10,000); Unknown (unable to determine with the data available.

In very rare cases, uncontrolled use, i.e. long-term and/or too frequent use, may result in keratopathy, hypopyon, or central corneal erosion including central scarring. Corneal perforation may also be possible.
Transient irritation, stinging and blurring of vision may occur on instillation.
In rare cases, local anaesthetic preparations have been associated with allergic reactions (in the most severe instances, anaphylactic shock).

Table 1.

Eye disorders:	
Unknown:	Eye pain, eye irritation, blurred vision, keratopathy, hypopyon, corneal erosion, corneal perforation, eye allergy, allergic blepharitis.
Immune system disorders:	
Unknown:	Hypersensitivity, anaphylactic reaction/shock.

Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after authorisation 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 via the HPRA Reporting Scheme; Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Overdosage following the recommended use is unlikely.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

5.2 Pharmacokinetic properties

The loss rate of local anaesthetics in the tears 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 peak time of effect of local anaesthetics. The non-ionised base of oxybuprocaine is rapidly absorbed from the pre-corneal tear film by the lipid containing 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 oxybuprocaine 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: 15 months.
For single use only. Discard immediately after use.

6.4 Special precautions for storage

Do not store above 25°C. Keep container in outer carton. 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. Overwrapped in an individual polypropylene/paper pouch. Each container holds approximately 0.5 ml of solution. Each carton contains 20 Minims units.

6.6 Special precautions for disposal

Each Minims unit should be discarded after use.

7 MARKETING AUTHORISATION HOLDER

Bausch + Lomb Ireland Limited
3013 Lake Drive
Citywest Business Campus
Dublin 24
D24 PPT3
Ireland

8 MARKETING AUTHORISATION NUMBER

PA23259/015/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1980

Date of last renewal: 01 April 2010

10 DATE OF REVISION OF THE TEXT

June 2022