SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Minims Oxybuprocaine Hydrochloride 0.4% w/v

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Single-use, clear, colourless, sterile eye drops, available as a 0.4% w/v solution of Oxybuprocaine Hydrochloride.

3 PHARMACEUTICAL FORM

Single-use sterile eye drops

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

As a topical ocular anaesthetic.

4.2 Posology 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 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.

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, oxybuprocaine 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 medicinal products and other forms of interaction

None stated.

4.6 Pregnancy, fertility 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); Not known (cannot be estimated from the current available data).

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	
Not known:	Eye pain, eye irritation, blurred vision, keratopathy, hypopyon, corneal erosion, corneal perforation, eye allergy, allergic blepharitis.
Immune system disorders:	
Not known:	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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Overdose following the recommended use is unlikely.

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 oxybuprocaine 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, 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

6.4 Special precautions for storage

Store below 25°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 disposal

Each Minims unit should be discarded after use.

7 MARKETING AUTHORISATION HOLDER

Bausch & Lomb UK Limited

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8 MARKETING AUTHORISATION NUMBER(S)

PL 03468/0053

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19/05/1987

10 DATE OF REVISION OF THE TEXT

31/03/2020