SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Minims Proxymetacaine hydrochloride 0.5% w/v, Eye Drops, solution.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Proxymetacaine hydrochloride 0.5%w/v.

For excipients see section 6.1

3 PHARMACEUTICAL FORM

Eye drops, solution.

Clear, colourless to pale yellow solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

To be used as a topical ocular anaesthetic.

4.2 Posology and method of administration

Adults (including the elderly) and children:

Deep anaesthesia: Instil 1 drop every 5 - 10 minutes for 5 - 7 applications.

Removal of sutures: Instil 1 or 2 drops 2 to 3 minutes before removal of stitches.

Removal of foreign bodies: Instil 1 or 2 drops prior to operating.

Tonometry: Instil 1 or 2 drops immediately before measurement.

Do not use if the solution is more than pale yellow in colour.

Each Minims unit should be discarded after a single use

A period of at least one minute should be allowed after administration of Minims Proxymetacaine hydrochloride 0.5% w/v, before subsequent administration of other topical agents.

4.3 Contraindications

Do not use in patients with a known hypersensitivity to any component of the preparation.

In view of the immaturity of the enzyme system which metabolises the ester type local anaesthetics in premature babies, this product should be avoided in these patients.

4.4 Special warnings and precautions for use

This product should be used cautiously and sparingly in patients with known allergies, cardiac disease or hyperthyroidism because of the increased risk of sensitivity reactions.

This product is not intended for long term use. Regular and prolonged use of topical ocular anaesthetics e.g. in conjunction with contact lens insertion, may cause softening and erosion of the corneal epithelium, which could produce corneal opacification with accompanying loss of vision.

Minims Proxymetacaine hydrochloride 0.5% w/v is not miscible with fluorescein, however, fluorescein can be added to the eye after it has been anaesthetised with Minims Proxymetacaine hydrochloride 0.5% w/v..

Protection of the eye from rubbing, irritating chemicals and foreign bodies during the period of anaesthesia is very important. Patients should be advised to avoid touching the eye until the anaesthesia has worn off.

Tonometers soaked in sterilising or detergent solutions should be thoroughly rinsed with sterile distilled water prior to use.

Systemic absorption may be reduced by compressing the lacrimal sac at the medial canthus for a minute during and following 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 in an inflamed eye as hyperaemia greatly increases the rates of systemic absorption through the conjunctiva.

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

4.6 Fertility, Pregnancy and lactation

Safety for use in pregnancy and lactation has not been established, therefore, use only when considered essential by the physician.

4.7 Effects on ability to drive and use machines

May cause transient blurring of vision on instillation. Warn patients not to drive or operate hazardous machinery unless vision is clear.

4.8 Undesirable effects

Pupillary dilatation or cycloplegic effects have rarely been observed with Proxymetacaine hydrochloride preparations. Irritation of the conjunctiva or other toxic reactions have occurred only rarely. A severe, immediate-type apparently hyperallergic corneal reaction may rarely occur. This includes acute, intense and diffuse epithelial keratitis; a grey ground-glass appearance; sloughing of large areas of necrotic epithelium; corneal filaments and sometimes, iritis with descemetitis.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Proxymetacaine hydrochloride, in common with other local anaesthetics, reversibly blocks the initiation and conduction of nerve impulses by decreasing the permeability of the neuronal membrane to sodium ions.

The delay to onset of effect, duration of effect and potency of Proxymetacaine hydrochloride are similar to those of amethocaine.

5.2 Pharmacokinetic properties

Proxymetacaine hydrochloride is readily absorbed into the systemic circulation where, in common with other ester-type local anaesthetics, it is hydrolysed by plasma esterases. Proxymetacaine hydrochloride is also subject to hepatic metabolism.

5.3 Preclinical safety data

No adverse safety issues were identified during the development of this formulation. The ingredients are well established in clinical ophthalmology.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified water
Hydrochloric acid
Sodium hydroxide

6.2 Incompatibilities

None known.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store at 2 - 8°C. Do not freeze. Keep container in the outer carton.

If necessary, the product may be stored at temperatures not exceeding 25°C for up to 1 month only.

6.5 Nature and contents of container

A sealed conical shaped polypropylene container fitted with a twist and pull off cap. Each Minims unit contains approximately 0.5ml of solution. Each unit is overwrapped in a polyethylene sachet. 20 units are packed into a suitable carton.

6.6 Special precautions for disposal

Each Minims unit should be discarded after a single use

If the product is to be stored unrefrigerated at temperatures not exceeding 25°C, prior to supply of the product by the pharmacy the adhesive label provided in the carton should be completed and affixed over the bar code, by a pharmacist. An expiry date one month from the supply date, plus the pharmacist's initials, should be written in the spaces provided on this label.

7 MARKETING AUTHORISATION HOLDER

Bausch & Lomb UK Limited
Bausch & Lomb House
106 London Road
Kingston-Upon-Thames
Surrey, UK

KT2 6TN

8 MARKETING AUTHORISATION NUMBER(S)

PL 03468/0080

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

13/11/2015

10 DATE OF REVISION OF THE TEXT

27/11/2015