# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Minims Tetracaine Hydrochloride 0.5% w/v Eye Drops, Solution

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Contains Tetracaine hydrochloride 0.5% w/v solution.
Each unit (0.5ml) contains Tetracaine hydrochloride 2.5mg.

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

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

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

Ocular anaesthetic for topical instillation into the conjunctival sac.

### 4.2 Posology and method of administration

Adults and children
One drop or as required. Each Minims unit should be discarded after use.

### 4.3 Contraindications

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

Tetracaine is hydrolysed in the body to p-amino-benzoic acid and should not therefore be used in patients being treated with sulphonamides.

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

### 4.4 Special warnings and precautions for use

The anaesthetised eye should be protected from dust and bacterial contamination.
Use with caution in an inflamed eye, as hyperaemia greatly increases the rate of systemic absorption through the conjunctiva.
Tetracaine may give rise to dermatitis in hypersensitive patients.
On instillation an initial burning sensation may be experienced. This may last for up to 30 seconds.
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 nasolacrimal 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 interactions

Tetracaine should not be used in patients being treated with sulphonamides (see 4.3 above).

**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**

Tetracaine may give rise to dermatitis in hypersensitive patients.
On instillation an initial burning sensation may be experienced. This may last for up to 30 seconds.
Corneal disorders such as superficial punctuate keratitis or edema may be observed following short-term application of Tetracaine (amethocaine) eye drops for topical anaesthesia.
The cornea may be damaged by prolonged application of anaesthetic eye drops.

**4.9 Overdose**

Not expected.

**5 PHARMACOLOGICAL PROPERTIES**

**5.1 Pharmacodynamic properties**

Tetracaine hydrochloride is used as a local anaesthetic which acts by reversibly blocking the propagation and conduction of nerve impulses along nerve axons. Tetracaine stabilises the nerve membrane, preventing the increase in sodium permeability necessary for the production of an action potential.

**5.2 Pharmacokinetic properties**

Tetracaine is a weak base ($pK_a$ 8.5), therefore, significant changes in the rate of ionised lipid soluble drug uptake may occur with changes in the acid base balance.

In vitro studies have shown that tetracaine has a high affinity for melanin, therefore, differences in duration of action may be expected between deeply pigmented eyes and less pigmented eyes.

The primary site of metabolism for tetracaine is the plasma. Pseudocholinesterases in the plasma hydrolyse tetracaine to 4-aminobenzoic acid. Unmetabolised drug is excreted in the urine.

**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**

Not applicable.

**6.3 Shelf life**

Unopened: 18 months.

**6.4 Special precautions for storage**

Do not store above 25°C. Store in the original package in order to protect from light.
Do not freeze.

**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 of a used medicinal product or waste materials derived from such medicinal product and other handling of the product**

For single use only. Discard any remaining contents.

**7 MARKETING AUTHORISATION HOLDER**

Bausch + Lomb Ireland Limited
3013 Lake Drive
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Dublin 24
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**8 MARKETING AUTHORISATION NUMBER**

PA23259/022/001

**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