Summary of Product Characteristics

TETRACAINE 0.5%

1. Name of the medicinal product

TETRACAINE 0.5%

2. Qualitative and quantitative composition

Each 1 mL contains tetracaine hydrochloride 5 mg

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Eye drops, solution

Clear, colorless to slightly yellow sterile ophthalmic solution

4. Clinical particulars

4.1 Therapeutic indications [1]

TETRACAINE 0.5% is indicated for procedures requiring a rapid and short-acting topical ophthalmic anesthetic.

4.2 Posology and method of administration [1]

Posology

One drop topically in the eye as needed. Discard unused portion.

4.3 Contraindications [2]

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 [1]

Corneal Injury with Intracameral Use

Not for injection or intraocular use. Do not use intracamerally because use of TETRACAINE 0.5% may lead to damage of the corneal endothelial cells.

Corneal Toxicity

Prolonged use or abuse may lead to corneal epithelial toxicity and may manifest as epithelial defects which may progress to permanent corneal damage.

Corneal Injury Due to Insensitivity

Patients should not touch the eye for at least 10-20 minutes after using anesthetic as accidental injuries can occur due to insensitivity of the eye.

Pediatric Use

Safety in the pediatric population has been demonstrated in clinical trials. Efficacy of TETRACAINE 0.5% for use in pediatric patients has been extrapolated from adequate and well controlled clinical trials in the adult population.

Geriatric Use

No overall differences in safety or effectiveness of TETRACAINE 0.5% have been observed between elderly and younger patients.

4.5 Interaction with other medicinal products and other forms of interaction [2]

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

4.6 Fertility, pregnancy, and lactation [1]

Pregnancy

Risk Summary

There are no adequate and well-controlled studies with TETRACAINE 0.5% in pregnant women. Animal developmental and reproductive toxicity studies with tetracaine hydrochloride have not been reported in the published literature.

Lactation

Risk Summary

There are no data to assess whether TETRACAINE 0.5% is excreted in human milk or to assess its effects on milk production/excretion. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for TETRACAINE 0.5% and any potential adverse effects on the breastfed child from TETRACAINE 0.5% or from the underlying maternal condition.

Females and Males of Reproductive Potential

No human data on the effect of TETRACAINE 0.5% on fertility are available.

4.7 Effects on ability to drive and use machines [2]

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 [1]

The following serious ocular adverse reactions are described elsewhere in the labeling:

- Corneal injury with Intracameral Use (see section 4.4)
- Corneal Toxicity (see section 4.4)
- Corneal Injury due to Insensitivity (see section 4.4)

The following adverse reactions have been identified following use of TETRACAINE 0.5%. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Ocular Adverse Reactions

Transient stinging, burning, and conjunctival redness, eye irritation, eye pain, ocular discomfort

4.9 Overdose [1]

Prolonged use of a topical ocular anesthetic including TETRACAINE 0.5% may produce permanent corneal opacification and ulceration with accompanying visual loss. Symptoms related to systemic toxicity consist mainly of effects on the neurologic and cardiovascular systems.

5. Pharmacological properties [1]

5.1 Pharmacodynamic properties

Mechanism of action

Tetracaine blocks sodium ion channels required for the initiation and conduction of neuronal impulses thereby affecting local anesthesia.

Clinical studies

Topical administration of TETRACAINE 0.5% results in localized temporary anesthesia. The maximum effect is achieved within 10–20 seconds after instillation, with efficacy lasting 10–20 minutes. Duration of effect can be extended with repeated dosing. (see section 4.4, 4.9)

5.2 Pharmacokinetic properties [1]

The systemic exposure to tetracaine following topical ocular administration of TETRACAINE 0.5% has not been studied. Tetracaine hydrochloride is metabolized by plasma pseudocholinesterases and nonspecific esterases in ocular tissues.

5.3 Preclinical safety data [1]

Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies to assess the genotoxicity of tetracaine hydrochloride have not been reported in the published literature. Long-term animal studies have not been conducted to evaluate the carcinogenic potential of tetracaine hydrochloride.

Animal studies to assess the effects of tetracaine hydrochloride on fertility have not been reported in the published literature.

6. Pharmaceutical particulars

6.1 List of excipients

Sodium chloride

Hydrochloric acid solution

Water for injection

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store below 30°C

Discard 24 hours after opening

6.5 Nature and contents of container

LDPE plastic tube 1 and 2 mL packed in aluminium sachet of 10 tubes and packed in paper box of 3 sachets.

LDPE plastic bottle 5 mL packed in paper box of 1 bottle.

7. Marketing authorization holder

Millimed BFS Co., Ltd.

174, 179 Moo 8, Pha Ngam, Wiang Chai,

Chiang Rai, 57210, Thailand.

Tel. 0 2945 9555

8. Marketing authorization number(s)

1A 99/67

9. Date of first authorization/renewal of the authorization

17 September 2024

10. Date of revision of the text

25 March 2024