

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Optrex 13% v/v Eye Drops, Solution.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Hamamelis Water (Distilled Witch Hazel) 13 % v/v.

Also contains Ethanol 2% v/v and Benzalkonium chloride 0.01% v/v.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye Drops, Solution.

A clear or practically clear, colourless solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As a topical preparation for relief of mild degrees of irritation, inflammation and congestion such as may occur with allergic conjunctivitis, blepharitis, exposure to external irritants.

4.2 Posology and method of administration

For topical administration into the eye.

For adults, children and the elderly;

Gently squeeze one or two drops into each eye.

Use as often as required.

4.3 Contraindications

Hypersensitivity to any of the ingredients.

Use in the presence of ulceration of the eye or obvious infection.

Not suitable for use with hydrophilic (soft) contact lenses.

4.4 Special warnings and precautions for use

For external use only.

Not suitable for use with hydrophilic (soft) contact lenses.

Contains benzalkonium chloride which may cause eye irritation. Avoid contact with soft contact lenses. Remove contact lenses prior to application and wait at least 15 minutes before reinsertion. Known to discolour soft contact lenses.

Keep out of the reach and sight of children.

Discard any eye drops remaining 28 days after opening the container.

4.5 Interaction with other medicinal products and other forms of interaction

No clinically significant drug interactions known.

4.6 Fertility, pregnancy and lactation

The safety of Optrex eye drops solution during pregnancy and lactation has not been established but it is not thought to constitute a hazard.

4.7 Effects on ability to drive and use machines

No adverse effects are known.

4.8 Undesirable effects

Occasional hypersensitivity reactions

4.9 Overdose

In view of the size of the container, overdosage should not be a problem and any treatment should only be symptomatic.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Hamamelis water has cooling and astringent properties.
Glycerol has lubricating and moisturising properties.

5.2 Pharmacokinetic properties

Not available.

5.3 Preclinical safety data

There are no preclinical safety data of relevance to the consumer.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Boric Acid
Borax
Glycerol
Benzalkonium chloride
Purified water
Ethanol

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years (unopened).
28 days (after first opening).

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

LDPE plastic bottle with a polyethylene dropper plug and a tamper evident HDPE plastic cap. Pack sizes of 10 ml and 18 ml.

Not all pack sizes may be marketed.

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

Do not use if the drops change colour or become cloudy.

7 MARKETING AUTHORISATION HOLDER

Optrex Limited
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1 Thane Road West
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8 MARKETING AUTHORISATION NUMBER

PA 275/6/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st April 1983

Date of last renewal: 1st April 2008

10 DATE OF REVISION OF THE TEXT

November 2011