SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Optrex Sore Eye Drops

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active
Distilled Witch Hazel BPC l3%v/v

(Synonyms: Hamamelis Water, Witch Hazel)

3. PHARMACEUTICAL FORM

Eye Drops

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of minor eye irritations caused by dusty or smoky atmospheres, driving or close work.

4.2 Posology and method of administration

For topical application 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 Contra-indications

Hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

For external use only.

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

Keep all medicines out of the sight and reach of children.

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

4.5 Interactions with other medicaments and other forms of interaction

No clinically significant drug interactions known.

4.6 Pregnancy and lactation

The safety of Optrex Sore Eyes Eye Drops during pregnancy and lactation has not been established but use during these periods is not considered to constitute a hazard.

4.7 Effects on ability to drive and use machines

No adverse effects known.

4.8 Undesirable effects

Occasional hypersensitivity reactions.

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

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. Pharmalogical Properties

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Hamamelis water has cooling and astringent 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
Glycerin
Benzalkonium chloride
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

a) Unopened: 36 months
b) After first opening: 28 days

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

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

6.6 Instruction for use, handling and disposal

None.

7. MARKETING AUTHORISATION HOLDER

Optrex Limited
103-105 Bath Road
Slough
SL1 3UH
UK

8. MARKETING AUTHORISATION NUMBER

PL 00062/5003R

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

15 May 1987

10 DATE OF REVISION OF THE TEXT

30/06/2017