SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Optrex Bloodshot Eye Drops

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Actives		
Hamamelis water*	BPC	12.5% v/v
Naphazoline hydrochloride	EP	0.01% w/v

*(*Synonyms. Distilled witch hazel, Witch hazel)*

Excipients with known effect: Benzalkonium chloride

For full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Eye drops

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

For temporary relief of redness of the eye due to minor eye irritations.

4.2 Posology and method of administration

Posology
Adults, children over 12 years and the elderly:
Gently squeeze one to two drops into the corner of each eye. No more than 4 times daily.

Children under 12 years:
Do not use.

Method of Administration
For topical application to the eye.

4.3 Contraindications

Hypersensitivity to hamamelis water, naphazoline, or to any of the excipients listed in section 6.1.

This product is contraindicated in persons suffering from closed-angle glaucoma.

Do not take if you are suffering from serious eye disease or have had previous eye surgery.

Do not use while taking monoamine oxidase inhibitors or within 14 days of stopping this medication (see section 4.5).

Not to be used in children younger than 12 years of age.

This product must not be administered while soft (hydrophilic) contact lenses are worn (see section 4.4). Soft contact lenses must be removed prior to use and reinserted after a minimum of 15 minutes.

4.4 Special warnings and precautions for use

Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards (see section 4.3).

If you are being treated for high blood pressure, depression, heart disease, arteriosclerosis, diabetes or increased thyroid activity consult your doctor before using the drops as naphazoline may exacerbate vasoconstriction. For the same reason this product should not be used as a long term ocular irrigant.

Discard any eye drops remaining 28 days after opening the container.
Continued use of this product may increase redness of the eye.

Use of naphazoline in the eye may liberate pigment granules from the iris, especially when given in high doses to elderly patients.
Benzalkonium chloride has been reported to cause eye irritation, symptoms of dry eyes and may affect the tear film and corneal surface. Should be used with caution in dry eye patients and in patients where the cornea may be compromised. Patients should be monitored in case of prolonged use.

If you experience eye pain, changes in vision or continued redness of the eye, or if the condition worsens or persists for more than 24 hours consult a doctor.

If the solution changes colour or becomes cloudy do not use.

4.5. Interaction with other Medicinal Products and other Forms of Interaction

May interact with other topically applied autonomic drugs used in the treatment of glaucoma. May interact with monoamine oxidase inhibitors and should not be used by patients receiving such treatment or within 14 days of ceasing therapy. May reverse the antihypertensive action of drugs used in the

treatment of hypertension. There may be an increased risk of arrhythmias in patients receiving cardiac glycosides, quinidine or tricyclic antidepressants.

4.6 Fertility, pregnancy and lactation

Pregnancy
Although the safety of Optrex Red Eyes Eye Drops during pregnancy has not been established, it is unlikely that sufficient of the active ingredients will reach the foetus to be harmful.

Breast Feeding
Although the safety of Optrex Red Eyes Eye Drops during lactation has not been established, it is unlikely that sufficient of the active ingredients will reach the breast-fed infant to be harmful.

Fertility
No known effects.

4.7 Effects on ability to drive and use machines

Do not drive or operate machinery if vision is blurred. Topical hamamelis water and naphazoline have no or negligible other influence on the ability to drive and use machines.

4.8 Undesirable effects

Adverse events which have been associated with hamamelis water and naphazoline hydrochloride are given below, tabulated by system organ class and frequency. Frequencies are defined as: Very common (≥1/10); Common (≥1/100 to <1/10); Uncommon (≥1/1000 to <1/100); Rare (≥1/10,000 to <1/1000); Very rare (< 1/10,000); Not known (cannot be estimated from the available data). Within each frequency grouping, adverse events are presented in order of decreasing seriousness**.**

System Organ Class	Frequency	Adverse Events
Immune System Disorders	Not known	Hypersensitivity
Nervous System Disorders	Not known	Headache, dizziness
Eye Disorders	Not known	Eye irritation, eye pain, ocular hyperaemia[1]
Gastrointestinal Disorders	Not known	Nausea

Description of Selected Adverse Reactions

[1] Following long term use a rebound secondary hyperaemia may occur.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms

If applied in excessive quantities to the eye, it may give rise to irritation and stinging.

Post marketing data has shown that excessive systemic exposure, for example due to intentional or accidental overdose of naphazoline (including inadvertent oral ingestion), may lead to severe cardiovascular and/or cerebrovascular adverse reactions.

Excessive or long-term use of this product may result in allergic conjunctivitis, allergic blepharitis or rebound conjunctival hyperaemia. Prolonged use may also lead to epithelial xerosis which can exacerbate symptoms of irritation, pain and dryness experienced in allergic conjunctivitis.

Indiscriminate use of decongestants, such as naphazoline, in an irritated eye can induce papillary dilation and precipitate angle-closure glaucoma in eyes that have narrow anterior chamber angles.

Overdosage by mouth may cause nausea, headache, depression of the central nervous system with marked reduction of body temperature and symptoms of bradycardia, sweating, drowsiness and coma, particularly in children. In addition, may cause hypertension followed by rebound hypotension.

There are no or limited data on overdose of topical hamamelis water, but risks are negligible.

Management
Treatment of adverse effects should be symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Sensory Organs; Ophthalmologicals; Decongestants And Antiallergics; Sympathomimetics Used As Decongestants.

ATC Code: S01GA51

Naphazoline is a sympathomimetic amine with pronounced alpha adrenergic activity and as a consequence has vasoconstrictor activity.
Distilled witch hazel has astringent properties.

5.2. Pharmacokinetic Properties

Although there are no specific pharmacokinetic properties for this product, systematic absorption of naphazoline may take place following topical application.

5.3. Pre-clinical Safety Data

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

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

Glycerin
Boric acid
Borax
Disodium edetate
Benzalkonium chloride
Purified water

6.2. Incompatibilities

Not applicable.

6.3. Shelf-Life

a) Unopened: 24 months.
b) After first opening: 28 days.

6.4. Special Precautions for Storage

Store below 25°C.
Do not freeze.

6.5. Nature and Contents of Container

The product will be packed in a capped bottle consisting of an opaque white Low Density Polyethylene (LDPE) bottle and dropper nozzle insert, with an opaque, screw on Polypropylene (PP), dropper cap with tamper evident band.

Pack size: 10 ml.

6.6. Instructions for Use, Handling and Disposal

None.

7. MARKETING AUTHORISATION HOLDER

Optrex Limited
103-105 Bath Road
Slough
SL1 3UH

8. MARKETING AUTHORISATION NUMBER(S)

PL 00062/0024

9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

11 April 1978 / 08 July 1997

10 DATE OF REVISION OF THE TEXT

12/03/2026