Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Optrex Clear Eyes Eye Drops Solution Hamamelis Water 12.5% v/v Naphazoline Hydrochloride 0.01% w/v

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredients

Hamamelis Water (Distilled Witch Hazel) 12.5% v/v

Naphazoline Hydrochloride 0.01% w/v

Excipient(s) with known effect:
benzalkonium chloride 0.0025 mg/drop
ethanol 2.0 % v/v.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution
A colourless, clear or practically clear solution, practically free from particles and with the characteristic odour of witch hazel.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

Posology:
For use by adults and children over 12 years.
Gently squeeze 1 or 2 drops into each eye, no more than 4 times daily.
If symptoms do not resolve within 24 hours,the patient should see a healthcare professional. This product is intended for intermittent or occasional use and should not be used for more than 72 hours unless under medical supervision.

Children under 12 years: Not to be used (see section 4.3)

Method of administration
For topical application to th eeye

4.3 Contraindications

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

Persons suffering from closed-angle glaucoma, serious eye disease, or who have had previous eye surgery.

Use in patients taking monoamine oxidase inhibitors or within 14 days of stopping such medication (see section 4.5).

Use in patients with contact lenses.

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

4.4 Special warnings and precautions for use

Persons suffering from glaucoma, serious eye diseases or who have had previous eye surgery should not use this product.

Use with caution on an inflamed eye, as hyperaemia greatly increases the rate of systematic absorption through the conjunctiva.

If you are being treated for high blood pressure, arteriosclerosis, cardiovascular disease, depression, heart disease, diabetes or increased thyroid activity, consult your doctor before using the drops as naphazoline may exacerbate vasoconstriction. Because of these possible adverse events, ocular decongestants should not be used as ocular irrigants.

If you experience severe eye pain, changes of vision or discharge from the eye, or if the condition worsens or persists for more than one day consult your doctor. The puncta should be depressed after installation of the drops to reduce drainage through the nasolacrimal duct to the oral nasal mucosa.

Discard any eye drops remaining 28 days after opening the container. If the solution changes colour or becomes cloudy do not use.

Use of naphazoline in the eye may liberate pigment granules from the iris, especially when given in high doses to elderly patients.

Continued use of this product may increase redness of the eye.

This medicine contains 0.0025 mg benzalkonium chloride in each drop.

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.

Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

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 increased risk of arrhythmias in patients receiving cardiac glycosides, quinidine or tricyclic antidepressants. This product contains Benzalkonium chloride which may interact with hydrophilic contact lenses.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are limited data from the use of hamamelis water and naphazoline in pregnant women. As a precautionary measure, it is preferable to avoid the use of the product during pregnancy unless recommended by the healthcare professional.

Breast-feeding
Although the safety of Optrex Clear Eyes Eye Drops during lactation has not been established, it is unlikely that sufficient of the active ingredients will reach the breast-fed infant. The product can be used during breast-feeding.

Fertility
No known effects.

4.7 Effects on ability to drive and use machines

This product may have a minor influence on the ability to drive and use machines. Dizziness may occur following administration of the product (see section 4.8) and vision may be blurred due to adding liquid to the eye.

4.8 Undesirable effects

Following long term use a rebound secondary hyperaemia may occur.
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 and <1/10); Uncommon (≥1/1000 and <1/100); Rare (≥1/10,000 and <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
Gastrointestinal disorders	Not known	Nausea

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 HPRA Pharmacovigilance Website: www.hpra.ie

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:S ensory Organs; Opthalmologicals; Decongestants and Antiallergics; Sympathomimetics Used as Decongestants.
ATC code: S01GA51

Naphazolineisa sympathomimeticamine with pronounced alpha adrenergenic activity and as a consequence has vasoconstrictor activity. Applied as an eye drop, it causes conjunctival vasoconstriction within 10 minutes. Effects can last for up to 6 hours.

Distilled witch hazel(hamamelis water) has coolingand astringent properties.

5.2 Pharmacokinetic properties

Although there are no specific pharmacokinetic particulars for this product, systematic absorption of naphazoline may take place following topical application. There are nor elevant pharmacokinetic data for hamamelis water.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride solution
Disodium edetate
Boric acid
Borax
Glycerol
Sodium hydroxide (for pH adjustment)
Hydrochloric acid (for pH adjustment)
Ethanol (component of distilled witch hazel)
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years – as packaged for sale.
28 days – after first opening of container.

6.4 Special precautions for storage

Do not store above 25°C.

Discard any remaining contents 28 days after first opening the container.

6.5 Nature and contents of container

A pigmented high density/low density polyethylene bottle having a polythene plug and wadless high density polyethylene tamper evident cap, containing 10ml.

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

Reckitt Benckiser Ireland Ltd,
7 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0979/079/001

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

February 2026