Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Refresh Ophthalmic 1.4%w/v + 0.6%w/v Eye Drops Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Polyvinyl alcohol	1.4	% w/v
Povidone	0.6	% w/v

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution
A clear, colourless solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As a lubricant and artificial tear in dry eye and other ocular irritation syndromes.

4.2 Posology and method of administration

Dosage schedule: Ensure container is intact. Twist off tab and apply one or two drops in each eye as needed, or as directed. No special dosage for the elderly or for children.

Route of administration: Ocular instillation.

4.3 Contraindications

Hypersensitivity to the active substances or any of the other excipients.

4.4 Special warnings and precautions for use

If irritation, pain, redness and changes in vision occur or worsen, treatment should be discontinued and a new assessment considered.

To avoid contamination or possible eye injury, the dropper tip should not be allowed to touch the eye or any other surface.

Contact lenses should be removed before each application and may be reinserted after 15 minutes.

Concomitant ocular medication should be administered 15 minutes prior to the instillation of Refresh Ophthalmic.

As Refresh Ophthalmic may delay penetration of other drugs, it should be used last if it is the more viscous product.

Do not use if solution changes colour or becomes cloudy.

4.5 Interaction with other medicinal products and other forms of interactions

No known drug interactions.

4.6 Fertility, pregnancy and lactation

Safety of the use of Refresh Ophthalmic during pregnancy and lactation has not been established. However, Polyvinyl alcohol and Povidone do not appear to be absorbed from the gastrointestinal tract and are not metabolised following injection.

4.7 Effects on ability to drive and use machines

Refresh Ophthalmic has minor or moderate influence on the ability to drive and use machines as it may cause transient blurring of vision. Do not drive or use hazardous machinery unless vision is clear.

4.8 Undesirable effects

Refresh Ophthalmic may cause transient stinging or irritation on instillation.

The frequency of the following undesirable effects is not known (cannot be estimated from the available data).

Eye disorders
- Eye irritation
- Eye pain
- Ocular hyperaemia
- Vision blurred
- Eye pruritus
- Foreign body sensation
- Eye discharge
- Hypersensitivity
- Conjunctival hyperaemia
- Lacrimation increased

4.9 Overdose

Systemic effects from topical overdose are not expected from the administration of Refresh Ophthalmic. Additionally, no toxic side effects are expected should accidental systemic overdose occur.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Artificial tears and other indifferent preparation- S01XA20.

REFRESH Ophthalmic exerts a mechanical, not a pharmacological action. The viscosity enhancing agent is Polyvinyl alcohol and the lubricating-enhancing agent is Povidone.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

The constituents of REFRESH Ophthalmic have been used safely in pharmaceutical products for many years. Topical administration in animal studies showed no untoward effects.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Sodium hydroxide (for pH adjustment)
Hydrochloric acid (for pH adjustment)
Purified Water

6.2 Incompatibilities

In the absence of compatibitlity studies this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

As packaged for sale: 2 years.

After first opening the container: Use immediately after opening. Discard any unused solution.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Low density polyethylene unit dose vials containing 0.4 ml of Refresh Ophthalmic.

Cartons contain 2, 5, 10, 15, 30, or 50 units per pack.

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

No special requirements.

7 MARKETING AUTHORISATION HOLDER

AbbVie Limited
Citywest Business Campus
Co Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA1824/013/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 07 March 1989

Date of last renewal: 07 March 2009

10 DATE OF REVISION OF THE TEXT

April 2022