

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Minims Saline 0.9% w/v Eye Drops, Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium Chloride 0.9% w/v.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Eye drops, solution

Single use, clear, colourless, sterile eye drops, solution

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As a topical ocular irrigating solution.

4.2 Posology and method of administration

Adults (including the elderly) and Children:

Adequate solution should be used to irrigate the eye.

4.3 Contraindications

None.

4.4 Special warnings and precautions for use

None.

4.5 Interaction with other medicinal products and other forms of interactions

None known.

4.6 Fertility, pregnancy and lactation

Not applicable.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

None known.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Minims Saline is an isotonic solution of sodium chloride used for irrigation of the eye. There are no pharmacodynamic properties of relevance for this product.

5.2 Pharmacokinetic properties

There are no pharmacokinetic properties which are applicable for this product.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

15 months

6.4 Special precautions for storage

Store below 25°C. Do not freeze. Store in the original container to protect from light.

6.5 Nature and contents of container

A sealed conical shaped container fitted with a twist and pull off cap made from Ph. Eur. grade polypropylene for containers and closures for parenteral and ophthalmic preparations. Each Minims unit contains approximately 0.5 ml of solution. Each unit is overwrapped in a polypropylene/paper pouch. 20 units are packed into a suitable carton.

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

Discard each unit after a single use.

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Bausch + Lomb Ireland Limited
3013 Lake Drive
Citywest Business Campus
Dublin 24
D24 PPT3
Ireland

8 MARKETING AUTHORISATION NUMBER

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

June 2022