

**Appendix 3**  
**SUMMARY PRODUCT CHARACTERISTIC**

**SUMMARY OF PRODUCT CHARACTERISTIC**  
**PHYSIODOSE – 0.9 solution of sodium chloride, in unidose**

**I.1. PRODUCT NAME**

PHYSIODOSE Physiological saline solution

**I.2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Sodium chloride (NaCl)..... 0.9 g,  
Purified water..... q.s. 100 mL.

**I.3. PHARMACEUTICAL FORM**

Unidoses of 5 mL

**I.4. CLINICAL DATA**

**I.4.1. Therapeutic indications**

The product recommended for babies, children, and adults:

- For nasal hygiene: to irrigate or cleanse dry or stuffed up noses,
- For ocular hygiene: as an eyewash or bath to cleanse the eyes,
- For auricular rinsing,
- For cleansing wounds,
- For inhalation in aerosoltherapy.

**I.4.2. Posology and method of administration**

**Posology:**

Do not use the same single-dose for the different uses.

The single-dose container is disposable and for individual use.

Detach a vial and open it by twisting off the top.

• For nasal hygiene

PHYSIODOSE Physiological saline solution may be used daily as a nasal and eye wash 1 to 6 times a day, as needed.

• For ocular hygiene

Pour a few drops of solution into each eye, taking care not to touch the surface of the eye with the vial.

• For ear hygiene

Use 1 vial of the product for both ears.

• For cleansing wounds

Rinse the wound, using the entire contents of one vial and taking care not to touch the wound with the vial.

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- For inhalation in aerosoltherapy

If the product is used as a solvent, follow the instructions included with the product for inhalation.

If the product is used alone, follow the instructions included with the inhalation equipment.

**Method of administration:**

- For nasal hygiene

Tilt the head back.

Delicately insert the tip into one nostril and gently squeeze the vial.

Repeat the operation in the other nostril.

Lift the head up to allow the mucous to run out and then wipe away the excess.

Do not blow your nose violently for 10 minutes after administering.

- For ocular hygiene

Pour a few drops of solution into each eye, taking care not to touch the surface of the eye with the vial.  
Wipe away excess liquid with a gauze.

- For ear hygiene

Rinse the external auditory canal with PHYSIODOSE Physiological saline solution.

Use 1 vial of the product for both ears.

Wipe away the surplus liquid with a gauze pad.

- For cleansing wounds

Rinse the wound, using the entire contents of one vial and taking care not to touch the wound with the vial.

- For inhalation in aerosoltherapy

If the product is used as a solvent, follow the instructions included with the product for inhalation.

If the product is used alone, follow the instructions included with the inhalation equipment.

### **I.4.3. Contraindications**

Not applicable.

### **I.4.4. Special warnings and precautions for use**

**Warnings**

Do not use a single-dose vial that is open or damaged due to the risk of rapid bacterial contamination.

Do not use after the expiry date stated on the single-dose vial.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

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**Precautions for use**

● For nasal hygiene

For babies, squeeze drops with a minimum amount of pressure to avoid any risk of contamination of the middle ear.

● For ocular hygiene

Wait 15 minutes before using any other eye treatment product.

● For cleansing wounds

Wipe away the excess liquid from the unaffected area only.

● For inhalation in aerosoltherapy

Ask your doctor for advice in case of first use or in case of respiratory hypersensitivity, of serious respiratory or cardiovascular pathologies.

**I.4.5. Interaction with other medicinal products and other forms of interaction**

No interaction studies have been performed.

**I.4.6. Fertility, pregnancy and lactation**

None.

**I.4.7. Effects on ability to drive and use machines**

Not applicable.

**I.4.8. Undesirable effects**

Not applicable.

**I.4.9. Overdose**

No case of overdose has been reported.

**I.5. PHARMACOLOGICAL PROPERTIES**

**I.5.1. Pharmacodynamic properties**

Pharmacotherapeutic group: NASAL PREPARATION  
OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS  
ALL OTHER NON-THERAPEUTIC PRODUCTS

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ATC code:                   R01AX10  
                                  S03D  
                                  V07AY

**I.5.2.      Pharmacokinetic properties**

-

**I.5.3.      Preclinical safety data**

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**I.6.        PHARMACEUTICAL PARTICULARS**

**I.6.1.      List of excipients**

Purified water.

**I.6.2.      Incompatibilities**

Not applicable.

**I.6.3.      Shelf life**

36 months.

**I.6.4.      Special precautions for storage**

Do not use a single-dose vial that is open or damaged due to the risk of rapid bacterial contamination.

Do not use after the expiry date stated on the single-dose vial.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

Store below 30°C.

**I.6.5.      Nature and contents of container**

Unidoses of 5 mL.

**I.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**

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

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**I.7.        MARKETING AUTHORISATION HOLDER**

Laboratoires Gilbert,  
928 Avenue du Général de Gaulle,  
14200 Hérouville Saint-Clair – FRANCE.

**I.8.        MARKETING AUTHORISATION NUMBER(S)**

< [To be completed nationally]>

**I.9.        DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

< { DD/MM/YYYY }> < { DD month YYYY }>

< [To be completed nationally]>

**I.10.      DATE OF REVISION OF THE TEXT**

< { MM/YYYY }>

< [To be completed nationally]>