# **ENGLISH VERSION**

## BOX

# PHYSIOLOGICAL SALINE

Sterile solution containing 0.9% of sodium chloride

XX single-dose vials (number of single-dose vials / box) of 5 mL or XX single-dose vials (number of single-dose vials / box) of 10 mL

#### **Preservative free**

## Do not inject

- Eye cleansing
- Nose cleansing

# **Composition:**

Sodium chloride: 0.9 g Purified water to 100 mL



# Precautions for use and warnings:

#### Do not inject. Single use only.

Do not re-use any opened single-dose vial. Discard it after use.

Do not use a single-dose vial damaged or included in damaged packaging.

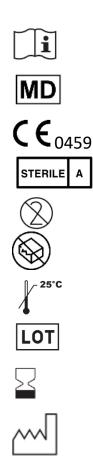
Do not use after the use-by date.

Keep the single-dose vials and the head of the vials out of reach and sight of children.

Do not use on injured eyes or nose.

Contraindicated in case of hypersensitivity to any of the components.

If pregnant or breastfeeding, seek medical advice before use.





UDI

Add pictograms/sorting instructions in accordance with local regulations.



UNITHER INDUSTRIES
Zone Industrielle Le Malcourlet
17 Avenue des Portes Occitanes
03800 GANNAT
France

#### **Distributor:**

Manufactured in France

# • LABEL OF SINGLE-DOSE VIAL

# **PHYSIOLOGICAL SALINE**

Do not inject















# • LEAFLET

# PHYSIOLOGICAL SALINE

Sterile solution containing 0.9% of sodium chloride

XX single-dose vials (number of single-dose vials / box) of 5 mL or XX single-dose vials (number of single-dose vials / box) of 10 mL

#### **Preservative free**

### Do not inject

#### Intended purposes and indications:

### Eye cleansing:

- Ocular foreign bodies (first-line treatment).
- Allergic and infectious conjunctivitis (first-line treatment for symptoms relief).

Nose cleansing: Nasal congestion in case of:

- Rhinitis linked to upper respiratory tract infections (first-line treatment).
- Allergic rhinitis (combined with a drug treatment).

#### Target patient group(s):

Infants, children, and adults.

#### Modes of action and clinical benefits:

# Eye cleansing:

- Ocular foreign bodies: Irrigation or application of a moistened cotton swab allows removal of contaminants by mechanical effect, reducing ocular discomfort, irritation, and pain.
- Infectious conjunctivitis: Irrigation or application of a cold compress allows removal of discharge and crusts by mechanical effect, thereby reducing symptoms.
- Allergic conjunctivitis: Applying a cold compress/cotton wool soaked in the solution acts by removing allergens from the eyes and constricting the conjunctival vessels, thereby reducing symptoms.

<u>Nose cleansing</u>: Ensures sufficient clearance of the nasal mucosa by mechanical effect. Contributes to the elimination of nasal secretions and mucociliary clearance, thus relieving nasal congestion and facilitating breathing.

#### **Composition:**

Sodium chloride: 0.9 g Purified water to 100 mL

#### Directions for use, intended users and environments:

Actions described below must be performed by an adult (healthcare professional or lay person), at home or in a medical environment.

The solution can be used daily with a maximum of 6 single-dose vials per day. [or 3 vials per day for single-dose vials of 10 mL]

Wash hands thoroughly before use. Separate a single-dose vial and open it by twisting the upper part.

① Discard the upper part immediately to avoid the risk of choking in infants and young children.

#### - Eye cleansing

<u>Presence of foreign bodies</u>: Tilt the head back. Irrigate the surface of the open eye to remove contaminants or use a cotton swab soaked in solution to gently sweep away the foreign body. <u>Infectious conjunctivitis</u>: Tilt the head back. Irrigate the surface of open eyes or apply a cold compress/cotton wool soaked in solution to remove discharge or crusts.

① Do not touch the surface of the eye with the tip of the single-dose vial.

<u>Allergic conjunctivitis</u>: Apply a cold compress/cotton wool soaked in the solution to the eyes to remove allergens.

Note: The solution is compatible with contact lenses except for the following type (not tested): Rigid lenses without hydrogel material, containing fluorine but not silicone.

This type of contact lenses must be removed before using the solution.

#### Nose cleansing

Tilt the head to the side then gently place the tip of the single-dose vial at the entrance of the nostril and squeeze the single-dose vial to irrigate the nasal cavity. Repeat the operation for the other nostril then wipe the nose and blow the nose if necessary.

In infants and young children, prefer a position lying on the side or on the stomach, keeping the head on the side to avoid the risk of choking and contamination of the middle ear.



## Do not inject. Single use only.

Do not re-use any opened single-dose vial, the absence of preservatives could lead to the administration of a contaminated solution. Discard it after use.

Do not use a single-dose vial damaged or included in damaged packaging.

Do not store above 25 °C. Not intended to be refrigerated or frozen.

Do not use after the use-by date.

Keep the single-dose vials and the head of the vials out of reach and sight of children.

Do not use on injured eyes or nose.

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

If pregnant or breastfeeding, seek medical advice before use.

# (1) Contra-indications, side-effects, and warnings:

Contraindicated in case of hypersensitivity to any of the components.

Potential non-serious side-effects:

Eye cleansing: Burning sensation, stinging, redness (frequency < 1%)

Nose cleansing: Nasal burning, nasal bleeding (frequency between 1 and 4 %)

If any side-effect occurs, consult a healthcare professional.

In case of deterioration of health or if no improvement is noted, consult a healthcare professional.

Any serious incident that has occurred in relation to the device must be reported to UNITHER INDUSTRIES and the competent authority of the Member State in which the user and/or patient is established.

Class IIb medical device.

Assistance contact: assistance@unither-pharma.com

Date of issue of the instructions for use: 2025-02.













UNITHER INDUSTRIES Zone Industrielle Le Malcourlet 17 Avenue des Portes Occitanes **03800 GANNAT** France

**Distributor:**