

ENGLISH VERSION

- **BOX**

Hyaluronate 0.2% NF

Sterile solution containing 0.2% of sodium hyaluronate.

XX single-dose vials (*number of single-dose vials / box*) of 0.25 mL

Preservative-free

Do not inject

Lubrication of the surface of the eyeball.

Composition:

100 mL of solution contains: sodium hyaluronate (0.20 g), sodium dihydrogen phosphate dihydrate, disodium hydrogen phosphate dodecahydrate, sodium chloride and water for injections.



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 eyes with a deep wound.

Wait at least 20 minutes between administration of two different ocular products.

Contra-indicated in case of hypersensitivity to any of the components.

If pregnant or breastfeeding, seek medical advice before use.

ACCOMPANYING DOCUMENTS – Hyaluronate 0.2% NF



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

- **POUCH**

Hyaluronate 0.2% NF

5 single-dose vials of 0.25 mL

Sterile and preservative-free solution containing 0.2% of sodium hyaluronate intended for ocular lubrication.

Do not inject.

In case of damaged single-dose vial, refer to the instructions for use.

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

After opening the pouch, keep the single-dose vials safe from the light and use them within 30 days.



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Distributor:

- LABEL OF SINGLE-DOSE VIAL

Hyaluronate 0.2% NF



LOT *(Laser marking on the single-dose vial)*

EXP *(Laser marking on the single-dose vial)*

- LEAFLET

Hyaluronate 0.2% NF

Sterile solution containing 0.2% of sodium hyaluronate.

XX single-dose vials (*number of single-dose vials / box*) of 0.25 mL

Preservative-free

Do not inject

Intended purpose and indication:

Lubrication of the surface of the eyeball in case of mild to moderate dry eye disease (first-line treatment).

Target patient group(s):

Adults (+ 18 years old).

Can be used by contact lens wearers after removal of lenses.

Mode of action and clinical benefit:

The solution contains sodium hyaluronate, a natural polymer present in eye tissues. This polymer is used for its lubricating and viscoelastic properties as well as for its water-holding capacity.

Sodium hyaluronate eye drops are known to increase tear film stability, maintain corneal moisture and reduce tear evaporation, thereby reducing the severity of dry eye symptoms from 5 minutes after instillation and for up to 6 hours.

Composition:

100 mL of solution contains: sodium hyaluronate (0.20 g), sodium dihydrogen phosphate dihydrate, disodium hydrogen phosphate dodecahydrate, sodium chloride and water for injections.

Directions for use, 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.

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

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

 **Contact lenses should be removed before instillation and replaced after 20 minutes.**

Gently pull your lower eyelid down, looking up.

Instill 1 or 2 drops into the eye and blink.

A single-dose vial allows treating both eyes, if necessary.

 **Do not touch the eyelids or eye surface with the tip of the single-dose vial.**

It is recommended to wait at least 20 minutes between two applications.

 Precautions for use:

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.

After opening the pouch, keep the single-dose vials safe from the light and use them within 30 days.

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 eyes with a deep wound.

Wait at least 20 minutes between administration of two different ocular products.

If pregnant or breastfeeding, seek medical advice before use.

 Contra-indications, side-effects, and warnings:

Contra-indicated in case of hypersensitivity to any of the components.

Non-serious side-effects (frequency between 1% and 10 %): Burning/stinging, foreign body sensation, sticky feeling, photophobia, conjunctivitis, dry eye, eye pain, eye irritation.

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.

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Assistance contact: assistance@unither-pharma.com

Date of issue of the instructions for use: 2026-01.



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