#### Instructions for use

Please read this information carefully because it will help you to use HYLO-FRESH® properly.

# **HYLO-FRESH®**

Sodium hyaluronate 0.03 % For relief of irritated eyes.

# Sterile, phosphate-free eye drops without preservatives



HYLO-FRESH® is a sterile, phosphate- and preservative-free solution for ocular use.

## Composition:

1 ml HYLO-FRESH® contains 0.3 mg sodium hyaluronate, Euphrasia-original mother tincture, boric acid, borax and water for injections.

# What is HYLO-FRESH® used for?

For relief of irritated eyes.

#### When should HYLO-FRESH® be used?

HYLO-FRESH® is used for the relief of irritated eyes. Irritated and dry eyes can result from environmental stress such as intensive computer-based activity, dry climate, draught, increased solar radiation, air pollution caused by dust or pollen or wearing contact lenses. For hundreds of years, preparations of eyebright (*Euphrasia officinalis*) have been traditionally used for the treatment of conjunctival irritation with red and burning eyes, increased secretion of tears, swelling and redness of the eyelids or eyelid margins.

HYLO-FRESH® contains sodium hyaluronate, which increases the viscosity of the moisturizing solution making it thicker than water. It therefore remains longer on the ocular surface. The application of the eye drops soothes irritated eyes and eyelids and provides them with a tear-like moistening effect. HYLO-FRESH® treats all symptoms caused by drying of the ocular surface, e.g. due to insufficient physiologic natural tear production by the body. HYLO-FRESH® also moistens the eyes of contact lens wearers.

Being preservative-free, HYLO-FRESH® is very well tolerated. Additionally, HYLO-FRESH® is phosphate-free, so that possible complications due to the formation of insoluble deposits in the cornea are avoided.

## How should HYLO-FRESH® be applied?

Please do not use HYLO-FRESH® if any part of the protective seal on the folding carton is broken or damaged before using for the first time (\$).



#### Step 1

Remove cap before use. To do this, hold the cap right above the bottle. With your other hand, pull away the bottle from the cap with a rotary movement. Before the first application please turn the HYLO-FRESH® bottle with its tip down and press down the bottom of the bottle repeatedly until the first drop appears at the nozzle dropper tip. Now the bottle is ready for further use.



# Step 2:

Hold the bottle upside down and place your thumb on the shoulder of the bottle and the other fingers on the base of the bottle.



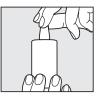
#### Step 3:

Support the hand holding the COMOD®-bottle with your other hand as shown.



#### Step 4:

With your head leaning back slightly, gently pull down your lower eyelid. Press down the base of the bottle vigorously and quickly. This activates the mechanism to release one drop. Because of the special COMOD® valve system, size and speed of each drop remain constant regardless of the pressure applied to the base of the bottle. Slowly close your eyes to allow the fluid to spread evenly on the eye surface.



#### Step 5:

Replace cap immediately and carefully after use. Ensure that the dropper tip is dry.
During use, please avoid any contact between the tip of the bottle and your eye or your skin.



Each bottle releases 10 ml of solution which is equivalent to approximately 300 drops.

For technical reasons a small amount of solution will remain in the bottle at the end of usage.

HYLO-FRESH® is only for you, even people with similar symptoms should not use your eye drops ( (1)).

#### What else do you need to know?

If you use another eye drop, it is recommended to wait at least 30 minutes after you have applied that eye drop, before you apply HYLO-FRESH®. Eye ointments should always be administered **after** using HYLO-FRESH®.

Because HYLO-FRESH® is preservative-free, it is well tolerated even when used over extended periods of time. In very rare cases, hypersensitivity reactions like burning or excessive tearing have been reported which have subsequently stopped immediately when the use of HYLO-FRESH® was discontinued.

HYLO-FRESH® may be used while wearing contact lenses. After inserting contact lenses, it is recommended to wait for about 30 minutes before applying the eye drops. In doing so, you avoid intolerance reactions which may occur due to interactions between lens care products and HYLO-FRESH®.

Based on the available findings HYLO-FRESH® may be used in children, pregnant and breast-feeding women.

In case a serious incident has occurred during the use of this medical device or as a result of its use, please report it to the manufacturer ( ).

# How often and for how long can you use HYLO-FRESH®?

HYLO-FRESH® should be used according to your condition. Generally, you instil one drop of HYLO-FRESH® three times a day into each eye. If necessary, you may use it more frequently. If you use HYLO-FRESH® more frequently (e. g. more than 10 times per day) please consult your eye doctor. HYLO-FRESH® is suitable for long-term treatment. Nevertheless, as with all complaints, you should consult your eye doctor if symptoms persist.

#### When should you not use HYLO-FRESH®?

Do not use HYLO-FRESH® if you are hypersensitive to one of the ingredients.

# What you need to know about storing HYLO-FRESH®?

Do not store above 25 °C ( $\sqrt[25 \circ C]{}$ ).

HYLO-FRESH® can be used for 6 months after first opening.

Do not use beyond expiry date ( $\supseteq$ ).

Keep out of the reach of children.

## The following package sizes are available:

10 ml of eye drops

7.5 ml of eye drops (sample pack)

#### Date of revision of the text:

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#### Manufacturer ::

URSAPHARM Arzneimittel GmbH Industriestraße 66129 Saarbrücken Germany

# and UK Responsible Person:

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Symbol:	Explanation:
wl	Manufacturer
	Distributor
MD	Medical device
CE	CE mark
STERILE A	Sterilized using aseptic processing techniques
<b>®</b>	Do not use if the outer packaging is damaged.
LOT	Lot number
$\subseteq$	Expiry date [YYYY-MM]
Ţ <u>i</u>	Read Instructions for use
₹ 25 °C	Do not store above 25°C.
(ii)	Single patient multiple use

