Please read this information carefully because it will help you to use HYCOSAN® ORIGINAL properly.

HYCOSAN® ORIGINAL

Soothing Relief of Dry Eyes

0.1% Hyaluronic Acid

To improve the lubrication of the eye surface in eyes that are dry, burning or have foreign body sensations due to environmental conditions as well as after ophthalmo-surgical interventions.

Sterile, phosphate and preservative free eye drops

What is HYCOSAN® ORIGINAL?

HYCOSAN® ORIGINAL is a sterile, phosphate- and preservativefree solution for ocular use.

Composition:

1 ml HYCOSAN® ORIGINAL contains 0.1% hyaluronic acid, citric acid anhydrous, sodium citrate, sorbitol and water for injections.

What is HYCOSAN® ORIGINAL used for?

To improve the lubrication of the eye surface in eyes that are dry, burning or have foreign body sensations due to environmental conditions as well as after ophthalmo-surgical interventions.

When should HYCOSAN® ORIGINAL be used?

If your eyes are itching, burning, or easily tiring, if it feels as if you had sand in your eyes, this might be due to a lack of moisture on the surface of your eyes. If you spent a longer time in an air-conditioned room, for example, or after intense computer work the natural tear film that usually covers the eye surface breaks up more quickly. For your eye tissue to be fully functioning, it needs to be continuously lubricated by a tear film.

Due to surgical interventions on the eye or after injuries of the eye the physiologic secretion of tears can be reduced. However, for the regeneration of the superficial tissues of the eye a continuous and sufficient lubrication is necessary. The application of HYCOSAN® ORIGINAL supplies long lasting moisture to cornea and conjunctiva so that the physiologic process of healing is efficaciously supported.

HYCOSAN® ORIGINAL contains the sodium salt of the hyaluronic acid, a natural substance that is found in the eye but also in other parts of the body. Due to its special physical property, it forms a regular, stable, long lasting lubricating moisture film on the ocular surface that is not easily rinsed off. It does, however, not cause blurred vision and protects your eyes from dryness and irritation for a long time.

This is particularly important if you wear contact lenses because the contact lens needs to swim in sufficient tear fluid in order not to cause any discomfort. HYCOSAN® ORIGINAL may be used while wearing contact lenses. Wearing contact lenses will be made more comfortable by using HYCOSAN® ORIGINAL as it does

As HYCOSAN® ORIGINAL is preservative-free it is usually very well tolerated. Additionally, HYCOSAN® ORIGINAL is free of phosphates so that complications like deposits in the cornea are avoided.

How should HYCOSAN® ORIGINAL be applied?

Please do not use HYCOSAN® ORIGINAL 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 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 HYCOSAN® ORIGINAL bottle with its tip down and press the bottom of the bottle repeatedly until the first drop appears at the nozzle. 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.



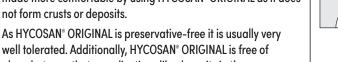
Step 4:

During use, please avoid any contact between the tip of the bottle and your eye or your skin. With your head leaning back slightly, gently pull down your lower eyelid. Press 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



Please contact the manufacturer in case of any questions about correct use of this medical device.

A bottle containing 7.5 ml of solution corresponds to approximately 225 drops. For technical reasons a small amount will remain in the bottle.

HYCOSAN® ORIGINAL can be used for an unlimited period of time.

HYCOSAN® ORIGINAL eye drops are only for you, even people with similar symptoms should not use your eye drops ((1)).

What else do you need to know?

If you do not feel better or if you feel worse after several days of use talk to your doctor or pharmacist.

If you use any other eye drops there should be at least 30 minutes between the applications, and HYCOSAN® ORIGINAL should always be used last. Eye ointments should, however, always be administered after using HYCOSAN® ORIGINAL.

Because it is preservative-free HYCOSAN® ORIGINAL is well tolerated even when used over a longer period of time. In very rare cases adverse reactions like hypersensitivity, burning or excessive tearing, pain, foreign body sensation or other temporary local irritations have been reported which stopped when the use of HYCOSAN® ORIGINAL was discontinued.

Please note that temporary blurred vision is possible after application of HYCOSAN® ORIGINAL due to the viscosity of the eye drops solution. In very rare cases this may cause temporary headache in sensitive patients.

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

Based on available evidence HYCOSAN® ORIGINAL can 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 HYCOSAN® ORIGINAL? Generally, you instil one drop of HYCOSAN® ORIGINAL three times a day into each eye. If you use HYCOSAN® ORIGINAL more frequently or when your complaints persist for more than one week, please consult your eye doctor or pharmacist.

When should you not use HYCOSAN® ORIGINAL?

HYCOSAN® ORIGINAL should not be used if you are hypersensitive to one of the ingredients.

What you need to know about storing HYCOSAN° ORIGINAL? Do no store above 25 °C ($\sqrt{^{25}$ °C).

HYCOSAN® ORIGINAL can be used for 6 months after opening.

Do not use beyond the expiry date (\cong).

Keep out of the reach of children.

Dispose this medical device via household waste according to your national legislation. This measure will help to protect the environment.

The following package sizes are available:

7.5 ml of eye drops

7.5 ml of eye drops (sample not for sale)

Date of information:

November 2022

URSAPHARM Arzneimittel GmbH Industriestraße 35 66129 Saarbrücken Germany

and UK Responsible Person

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MD

STERILE A

Cumb al.	Funlamentian.
Symbol:	Explanation:
	Manufacturer
	Distributor
MD	Medical device
C€	CE mark
STERILE A	Sterilized using aseptic processing techniques
®	Do not use if the outer packaging is damaged.
LOT	Lot number
\square	Expiry date [YYYY-MM]
[]i	Read Instructions for use
1 25 °C	Do not store above 25°C.
(in)	Single patient multiple use



