

Instructions for use

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

HYCOSAN® PLUS

Soothing hydrating relief and healing support to a damaged eye surface, due to dry eyes or post-surgery

Hyaluronic Acid 0.1% and 2% dexpanthenol

For lubrication and support of healing of a damaged surface of the eye e.g. due to dry eyes or surgical procedures.

Sterile, phosphate and preservative free eye drops.

What is HYCOSAN® PLUS?

HYCOSAN® PLUS is a sterile, phosphate- and preservative-free solution for ocular use.

Composition:

1 ml HYCOSAN® PLUS contains 0.1% hyaluronic acid, 2% dexpanthenol, citric acid anhydrous, sodium citrate and water for injections.

What is HYCOSAN® PLUS used for?

For lubrication and support of healing of a damaged surface of the eye e. g. due to dry eyes, or surgical procedures.

When should you use HYCOSAN® PLUS?

HYCOSAN® PLUS is indicated for the treatment of dry eye disease.

To regenerate and maintain the ocular surface - cornea and conjunctiva – it must be kept permanently moist. Normally our tears fulfil this role. However, in some cases there are not enough tears, or their composition is disturbed. In these cases, the eye reacts with redness, itching, foreign body and burning sensation, or acute tiredness. These symptoms of an inadequate supply with physiologic tears may occur in dry or air-conditioned environments, as well as result of medical treatment or – purely – due to age.

The epithelial cells of cornea and conjunctiva are continuously restored, and this process works best in a humid environment. Therefore, after surgical procedures it is vital that the ocular surface is sufficiently lubricated to allow proper wound healing.

In all these cases it is advisable to apply intensive humidity to the eye by using HYCOSAN® PLUS in order to renew the physiologic balance of lubrication and moisturisation of the eye.

HYCOSAN® PLUS contains the sodium salt of hyaluronic acid, a physiologic substance of the eye but also of other parts of the body. Hyaluronic acid has unique properties which allow it to form an even and long-lasting lubricating film on the surface of the eye without being rinsed away quickly. Consequently, the moisturising effect is prolonged without impairing vision. Therefore, HYCOSAN® PLUS can be used during the day while eye ointments and gels can cause blurred vision because of their greasy consistency.

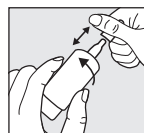
Additionally, HYCOSAN® PLUS contains dexpanthenol which belongs to the extensive group of B vitamins. This component assists the eye during its phase of intensive regeneration while the lubricating properties of hyaluronic acid further support this process.

In addition to this, dexpanthenol supports wound healing and so superficial erosions on the ocular surface caused by an insufficient tear film as well as wounds which are sometimes the result of surgical procedures, can both heal faster.

HYCOSAN® PLUS ensures not only a sufficient supply of humidity to the eye but at the same time enhances the regeneration of corneal and conjunctival epithelia.

How should HYCOSAN® PLUS be applied?

Please do not use HYCOSAN® PLUS if any part of the protective seal on the folding carton is broken or damaged before using for the first time (☹).

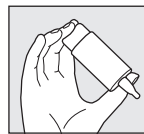


Step 1:

Remove cap before use.

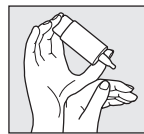
To do this, hold the cap above the bottle. With your other hand, pull away the bottle from the cap with a rotary movement.

Before the first application please turn the HYCOSAN® PLUS 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:

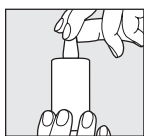
Support the hand holding the COMOD®-bottle with your other hand as shown.



Step 4:

When applying the eye drops, please avoid any contact between the tip of the bottle and your eye and 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 of solution will remain in the bottle.

HYCOSAN® PLUS is suitable for long term treatment and can be used by adults and children without limitation of age.

HYCOSAN® PLUS is only for you, even people with similar symptoms should not use your eye drops (👤).

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® PLUS should always be used last. Eye ointments should, however, always be administered after using HYCOSAN® PLUS.

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

HYCOSAN® PLUS 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® PLUS.

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

According to existing knowledge HYCOSAN® PLUS 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 HYCOSAN® PLUS?

Generally, you instil one drop of HYCOSAN® PLUS three times a day into each eye.

If you use HYCOSAN® PLUS 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® PLUS?

Do not use HYCOSAN® PLUS if you are hypersensitive to one of the ingredients.

What you need to know about storing HYCOSAN® PLUS?

Do not store above 25 °C (🕒^{25°C}).

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

Do not use beyond the expiry date (🕒).

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 packaging sizes are available:

7.5 ml of eye drops

7.5 ml of eye drops (sample not for sale)

Date of information:

November 2022

🏭 Manufacturer:

URSAPHARM Arzneimittel GmbH
Industriestraße 35
66129 Saarbrücken
Germany

🇬🇧 UK Responsible Person

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CE₀₁₉₇

MD

STERILE A

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