

Instructions for use

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

HYCOSAN® EXTRA

Soothing Relief of Persistent and Severe Dry Eyes

0.2% Hyaluronic Acid

For the intensive, therapeutic lubrication of the ocular surface in more severe and persistent dry eye sensation as well as after surgical interventions on the eye.

Sterile, phosphate and preservative free eye drops

What is HYCOSAN® EXTRA?

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

Composition:

1 ml HYCOSAN® EXTRA contains 0.2 % hyaluronic acid, citric acid anhydrous, sodium citrate, sorbitol and water for injections.

What is HYCOSAN® EXTRA used for?

HYCOSAN® EXTRA is an eye drop for the intensive, therapeutic lubrication of the ocular surface in more severe and persistent dry eye sensation including treatment after surgical interventions on the eye.

When should HYCOSAN® EXTRA be used?

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

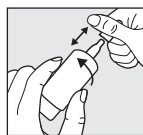
HYCOSAN® EXTRA contains the sodium salt of hyaluronic acid, a natural substance found in many organs of the human body including the eye. Its unique property is that it forms a regular, stable and long lasting, lubricating and moisturising film on the eye surface that is not easily rinsed off. This so-called bioadhesive property ensures that the cornea and conjunctiva are protected and together with the physiologic tears the eye lid moves easily over the surface of the eye. HYCOSAN® EXTRA contains a higher amount of hyaluronic acid which makes it more viscous and in so doing the eye is provided with an intensive, soothing and long-lasting moisturising film. Persistent or more severe symptoms are relieved, and the eye is protected against further irritation.

Due to surgical interventions on the eye or after eye injuries the physiologic tear secretion may be reduced. A continuous moisturising of the surface of the eye is necessary for the regeneration of the eye's tissues. By applying HYCOSAN® EXTRA increased moisture and lubrication is supplied to cornea and conjunctiva so that the physiologic wound healing process is optimal.

Being preservative-free HYCOSAN® EXTRA is usually very well tolerated. Additionally, HYCOSAN® EXTRA is free of phosphates so that possible complications due to the formation of insoluble deposits in the cornea are avoided.

How should HYCOSAN® EXTRA be applied?

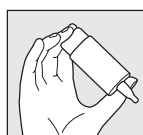
Please do not use HYCOSAN® EXTRA if any part of the protective seal on the folding carton is broken or damaged before using for the first time (☹).



Step 1:

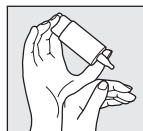
Remove the cap before use.

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® EXTRA 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.



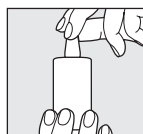
Step 3:

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, the 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 question 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 always remains in the bottle.

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

Each bottle HYCOSAN® EXTRA should be used only by the same person ().

What else do you need to know?

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

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

As HYCOSAN® EXTRA is preservative-free it 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 stop when the use of HYCOSAN® EXTRA is discontinued.

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

HYCOSAN® EXTRA relieves the symptoms in case of more severe or persistent dry eye sensation. HYCOSAN® EXTRA may be used while wearing contact lenses, in consultation with your eye specialist. However, in these cases, there may be some smearing on the contact lenses that will disappear after blinking a few times.

After inserting contact lenses, waiting for about 30 minutes before applying the eye drops is recommended. In this way, you avoid intolerance reactions which may occur due to interactions between lens care products and HYCOSAN® EXTRA.

Based on available evidence HYCOSAN® EXTRA 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® EXTRA?

Generally, you instil one drop of HYCOSAN® EXTRA three times a day into each eye. If necessary, it can also be used more frequently. If you use HYCOSAN® EXTRA more frequently (e. g. more than 10 times per day) or when your complaints persist, please consult your eye doctor or pharmacist.

When should you not use HYCOSAN® EXTRA?

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

What you need to know about storing HYCOSAN® EXTRA?

Do not store above 25 °C ( 25 °C).

HYCOSAN® EXTRA can be used for 6 months after first opening.

Do not use beyond 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 package sizes are available:

7.5 ml of eye drops

7.5 ml of eye drops (sample not for sale)

Date of information:

August 2024

 **URSAPHARM Arzneimittel GmbH**
Industriestraße 35
66129 Saarbrücken
Germany

 and UK Responsible Person

Scope Ophthalmics Ltd
1st Floor, Unit 4 Amberley Court,
Whitworth Road, County Oak Way,
Crawley, West Sussex, RH11 7XL
Freephone: 0808 175 3200
Fax: +44 203 515 9461
Email:
info@scopeeyecare.com
www.scopeeyecare.com

 0197





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