

Instruction for use

Please read this instruction carefully because it contains important information for you. Keep this leaflet. You may need to read it again. If you need more information or advice, please consult either your doctor or a pharmacist. You must contact a doctor if your symptoms worsen or do not improve.

HYCOSAN Shield®

For lubrication of dry, irritated eyes and stabilization of the tear film to relief symptoms of dry eyes
Sterile eye drops without phosphates or preservatives

PRODUCT DESCRIPTION

HYCOSAN Shield® is a medical device that contains a water-free, preservative-free eye drops liquid and does not contain phosphate.

COMPOSITION

HYCOSAN Shield® only contains perfluorohexyloctane (EyeSol®).

INTENDED PURPOSE

HYCOSAN Shield® is intended for lubrication of dry irritated eyes and for stabilization of the tear film and relief of symptoms associated with dry eyes.

MEDICAL INDICATION

Dry eye disease

SUITABLE FOR

HYCOSAN Shield® is suitable for adult patients.

Use in pregnant or breastfeeding women and children:

Due to the lack of safety data for the use in pregnant or breastfeeding women and children, the use of HYCOSAN Shield® is not recommended.

CLINICAL BENEFIT, PERFORMANCE AND EFFECTIVENESS

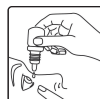
The clinical benefit is the relief from symptoms of dry eye disease.

GENERAL INSTRUCTIONS FOR USE

Due to its special properties HYCOSAN Shield® behaves differently to conventional eye drops when it is applied into the eye. Therefore, please read the instructions carefully before use.

1. Wash your hands before use.
2. Unscrew the cap of the eye drop bottle.
3. Following removal of the cap, avoid any contact with the dropper tip.

4. To avoid loss of solution please read the following steps carefully before applying the eye drops.
 - Hold the opened bottle with the dropper pointing upwards and gently press the bottle between thumb and index finger.
 - Keep the bottle under slight pressure and turn the bottle until the dropper points downwards.
 - With the dropper pointing downwards reduce the pressure on the bottle to allow some air to flow into the bottle.
5. Lean your head back slightly and carefully pull down your lower eyelid. Look upwards.
6. Hold the opened bottle with the dropper pointing downwards above your eye. Apply gentle pressure on the bottle and administer 1 drop per eye.
Note: Due to the special properties of HYCOSAN Shield® you may not feel the drop falling into your eye. In this case we recommend application in front of a mirror.
7. Do not touch the dropper with your eye or lashes.
8. For an even distribution, close your eyes after applying HYCOSAN Shield® for a moment.
9. Put the screw cap back on after administration.



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

HYCOSAN Shield® can be used for 6 months after first opening. Bottles with leftovers can be discarded with household garbage.

DOSAGE

Unless otherwise instructed by your physician or pharmacist, use 4 times daily squeezing one drop inside the lower eyelid. If necessary, HYCOSAN Shield® can be used daily.

WARNINGS AND PRECAUTIONS

Take special care with HYCOSAN Shield® if you are currently using other eye medication. If you use any other eye drop medication please allow at least 30 minutes after the application and before applying HYCOSAN Shield®. HYCOSAN Shield® should always be used last. Eye ointments should not be used during the treatment with HYCOSAN Shield®.

Do not use HYCOSAN Shield® if you wear contact lenses due to the lack of data concerning the compatibility of HYCOSAN Shield® with the contact lens materials.

SIDE EFFECTS

In single cases transient eye irritations like burning, itching or redness of the eye have been reported after the application of HYCOSAN Shield®. This could possibly indicate an allergic reaction. If you experience longer lasting irritation of the eyes, stop the treatment and seek advice at your doctor or pharmacist.

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 (🏭) and the competent authority of your Member State.

CONTRAINDICATIONS

Do not use HYCOSAN Shield® if you are hypersensitive (allergic) to the ingredient perfluorohexyloctane.

STORAGE

Do not store above 25 °C (🌡️ 25 °C).

Do not use HYCOSAN Shield® if the bottle or the original closure seal is damaged (🔍). Note the date of first opening on the outer packaging.

Do not use HYCOSAN Shield® after the imprinted expiry date (📅).

Keep out of the reach and sight of children.

Do not drink the liquid.

Any medical device you no longer use should be thrown away via household waste. This measure will help to protect the environment.

The following package sizes are available:

Pack of 3 ml eye drops.

Sample not for sale: pack of 1 ml eye drops.

For better handling, the eye drops are filled in bottles of 5 ml and are consequently only filled up to a half.

The filling process is constantly controlled in order to exclude an underfilling of the bottles.

Date of information: June 2024



URSAPHARM Arzneimittel GmbH

Industriestraße 35, 66129 Saarbrücken, Germany

www.ursapharm.de



and UK Responsible Person

UK: 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



Legend of pictograms:

	Manufacturer
	Distributor
	CE-mark
	Aseptic manufacturing
	Unique device identifier
	Medical device
	Do not use if the outer packaging is damaged
	Manufacturing date YYYY-MM is printed on the outer packaging
	Lot number is printed on the label and the outer packaging.
	Expiry date is printed on the label and the outer packaging
	Store at room temperature (not above 25 °C).
	Notice instruction for use
	Single patient multiple use