

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.

EvoTears®

For lubrication of dry, irritated eyes and stabilization of the tear film to relieve symptoms of dry eyes

Sterile eye drops without phosphates or preservatives

PRODUCT DESCRIPTION

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

COMPOSITION

EvoTears® only contains perfluorohexyloctane (EyeSol®).

INTENDED PURPOSE

EvoTears® 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

EvoTears® 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 EvoTears® 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 EvoTears® 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 EvoTears® 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 EvoTears® 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.

EvoTears® 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, EvoTears® can be used daily.

WARNINGS AND PRECAUTIONS

Take special care with EvoTears® 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 EvoTears®.

EvoTears® should always be used last.
Eye ointments should not be used during the treatment with EvoTears®.

Do not use EvoTears® if you wear contact lenses due to the lack of data concerning the compatibility of EvoTears® 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 EvoTears®. 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 EvoTears® if you are hypersensitive (allergic) to the ingredient perfluorohexyloctane.

STORAGE

Do not store above 25 °C (🌡️ 25 °C).
Do not use EvoTears® if the bottle or the original closure seal is damaged (🔍). Note the date of first opening on the outer packaging.
Do not use EvoTears® 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.

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CE 0197 MD STERILE A

Your opinion about our product is important to us.
We look forward to receiving your feedback via mail or via
www.ursapharm.info/evotears

Legend of pictograms:

🏭	Manufacturer
🇬🇧	Distributor
CE	CE-mark
STERILE A	Aseptic manufacturing
UDI	Unique device identifier
MD	Medical device
🔍	Do not use if the outer packaging is damaged
📅	Manufacturing date YYYY-MM is printed on the outer packaging
LOT	Lot number is printed on the label and the outer packaging.
🕒	Expiry date is printed on the label and the outer packaging
🌡️ 25 °C	Store at room temperature (not above 25 °C).
📖	Notice instruction for use
👤	Single patient multiple use