

**Patient leaflet in accordance with the Pharmacist's Regulations
(Preparations) 1986**

The medicine is dispensed without a doctor's prescription

EYECON

Eye drops

Sterile solution without a preservative

Composition: the active ingredient and its quantity:
Sodium Hyaluronate 0.15 mg/ml

Inactive ingredients: see section 6: "Additional Information".

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about the medicine.
If you have further questions, refer to the doctor or the pharmacist.

This medicine is intended for adults (over 18 years old). You should use the medicine according to the instructions given in the dosage section of this leaflet. Consult with the pharmacist if you need further information. Consult with the doctor if your dry eye symptoms get worse.

1. What is this medicine intended for ?

Eyecon is intended for treating symptoms of eye dryness (dry eye syndrome).

Therapeutic group: eye lubricants.

2. Before using this medicine

Do not use Eyecon:

- If you are sensitive (allergic) to the active ingredient or to any of the other ingredients of this medicine.
- In cases where there is an increased risk of internal or external inflammation of the eye (for instance after eye surgery or when a patient has a tendency to get inflammations).

Special warnings regarding the use of the medicine

Before using Eyecon, tell the doctor:

- If you have or have ever had impaired eye function (such as glaucoma).

There are no studies of the effect of Eyecon on intraocular pressure or effects on its measurement.

Children and adolescents:

Eyecon is not recommended for use in children and adolescents under 18 years of age due to lack of clinical experience in this age group.

Drug interactions:

If you are taking or have recently taken, other medicines including nonprescription medicines and nutritional supplements, tell the doctor or pharmacist. If you are being treated with other eye medicines, wait at least 5 minutes before applying Eyecon eye drops. Eyecon must be the last medicine you apply. Eyecon may be used while wearing contact lenses if the doctor approves using contact lenses in your medical condition.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine. Reproductive studies have not shown any risk as a result of using this medicine, but there are no controlled studies in pregnant women using it. Eyecon only has a physical effect on the eye and can therefore be used during pregnancy and breastfeeding.

Driving and using machines

Using this medicine may cause temporarily blurred vision immediately after applying the medicine until the eye drops are uniformly distributed. Therefore you must be cautious when driving, operating dangerous machines, and during any other activity that requires normal vision.

3. How should you use this medicine?

Check with your doctor or pharmacist if you are not sure.

Unless the doctor instructed you otherwise, the usual dose is:

Depending on how dry your eyes are- one drop, 4-8 times a day.

Do not exceed the recommended dose.

Do not swallow ! For use in the eyes.

Directions for use:

Wash your hands carefully.

The medicine's package contains strips of disposable containers (vials) wrapped in aluminium foil sachets. Open the foil sachet and remove the strip of disposable vials from it. Separate one vial from the strip by twisting the vial and not by pulling it (see figure 1, below).

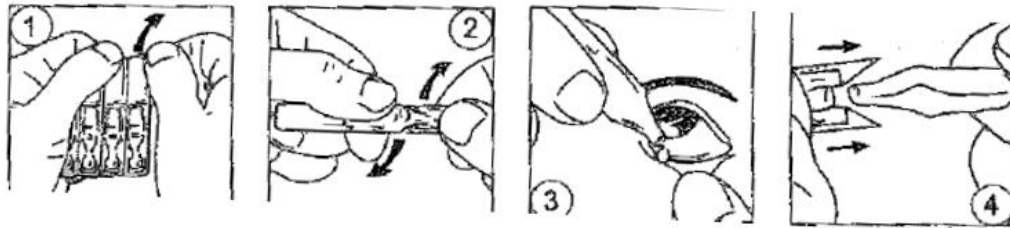
To open the disposable vial, turn the top part (see figure 2, below). Keep the vial cap.

Now, tilt your head back a little or lie down, look up and use your finger to

move your lower eyelid away from your eye. Apply one drop into the lower part of the conjunctival sac by gently pressing the bottom of the vial (see figure 3, below). To avoid contaminating the solution, make sure that the vial tip does not come into contact with any surface including your finger and eye.

Use the cap to close the vial (see figure 4).

Close your eyes gently for a few minutes.



This medicine is sterile as long as the plastic vial is intact. Do not use if the package is damaged.

Each vial can be recapped and then reused within 12 hours.

Do not use a vial if more than 12 hours have passed since first opening it, and do not share it with another person.

Can be used with all types of contact lenses.

If you accidentally used more than you should

To date no effects of Eyecon overdose have been reported.

If you forget to use Eyecon

If you forget to take the medicine at the prescribed time, do not take a double dose.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions about using this medicine, consult with your doctor or pharmacist.

4. Side effects

Like all medicines, using Eyecon may cause side effects in some users. Do not be alarmed at reading the list of side effects. You may not suffer from any of them.

Occasionally, there may be temporary side effects immediately after the application: burning sensation in your eye or blurred vision.

If you get a side effect, if one of the side effects worsens, or when you suffer from side effects not mentioned in this leaflet, consult with the doctor.

Reporting of side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Adverse Drug Reactions Report" that appears on the home page of the Ministry of Health website (www.health.gov.il), which leads to an online form for reporting side effects.

Alternatively you can use the following link:

<https://sideeffects.health.gov.il/>

5. How should the medicine be stored?

- Avoid poisoning! This medicine and all other medicines should be stored in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed by a doctor to do so.

- Do not use this medicine after the expiry date (exp. date) that is printed on the outer package/ label. The expiry date refers to the last day of that month.

- Storage conditions:

- store at temperature below 25°C.

- Keep the vials inside the inner sachets and in the original outer package to protect their content from light.

- After opening a disposable vial, use it within 12 hours and then discard the vial.

- After opening the inner aluminium foil sachet, use the closed vials within 4 weeks only, and then discard them.

6. Additional information

- In addition to the active ingredient this medicine also contains:
Water for Injection , Glycerol, Carbomer 981.

This medicine does not contain a preservative.

- What the medicine looks like and what is the content of the package?

The package contains 20 or 30 disposable vials packed in inner aluminium foil sachets. Each vial contains 0.65 ml of eye drops. Not all package sizes may be marketed.

- Registration holder and its address:

GEM PHARMA Ltd., 12 YAKINTON ST., KFAR VRADIM 2514700

- Manufacturer name and address:

PHARMA STULLN GmbH, WERKSSTRASSE 3, STULLN 92551,
GERMANY .

- Registration number of the medicine in the National Drug Registry of the
Ministry of Health:

116-76-29346

- **Revised in February 2022 according to MoH guidelines.**
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