

The patient package insert in accordance with the pharmacists' regulations (preparations) – 1986

This medicine is dispensed without a doctor's Prescription

DURATEARS

Ocular Lubricating Ointment
Preservative Free

Composition: Anhydrous liquid lanolin 30 mg/g
Mineral oil 30 mg/g
White petrolatum ad 1 g

Read this package insert carefully in its entirety before using this medicine. This leaflet contains concise information on the medicine. If you have any further questions, refer to the doctor or to the pharmacist. You must use this medicine properly. Consult your pharmacist if you need additional information. You should refer to your doctor if the disease symptoms worsens or do not improve after 3 days.

1. What is this medicine intended for?

Therapeutic activity: Lubricating ointment intended to prevent ocular dryness.

Therapeutic group: eye preparations.

2. Before using the medicine:

Do not use the medicine if:

- You have a known sensitivity to any of the ingredients of the medicine,

Special warnings regarding use of the medicine:

- If you are sensitive to any type of food or medicine, inform the doctor before commencing treatment with this medicine.
- **Duratears** is intended for use in the eyes only.
- Do not wear contact lenses during treatment with this preparation.
- If you experience headache, eye pain or irritation of the eyes, vision changes or persistent redness in the eyes or if your condition worsens or persists for more than 3 days – discontinue the treatment and refer to your doctor.

Children

The safety and efficacy of DURATEARS eye ointment in children has not been determined.

If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, inform the doctor or pharmacist.

- If you are using other eye preparations (for instance, drops), you must wait at least 5 minutes between each application. Administer the eye ointment last.

Use of the medicine and food:

Food and drink have no influence on the treatment.

Pregnancy and breastfeeding:

Duratears can be used during pregnancy and breastfeeding.

If you are pregnant, are planning to get pregnant, or if you are breastfeeding, consult your doctor or pharmacist before using any medicine.

Driving and use of machines:

If your vision becomes blurred after using this preparation, do not drive or operate machines., until the vision becomes clear again.

DURATEARS contains lanoline (wool fat) which may cause local skin reactions (f.e contact dermatitis).

3. How should you use the medicine?

Always use this medicine as described in this leaflet, unless your doctor has told you differently. You should check with your doctor or pharmacist if you are not sure.

If your doctor has prescribed **Duratears** to you, your doctor will instruct you how long you should use this medicine. **Do not stop the treatment early.** The usual dose is the application of a small quantity of ointment in the eye(s), at night before going to bed.

Do not exceed the recommended dose.

You must wait at least 5 minutes between the application of this medicine and the application of other eye preparations.

If no improvement of your condition occurs within 3 days, refer to your doctor.

Attention: this medicine is intended for external use only.

Directions for use:

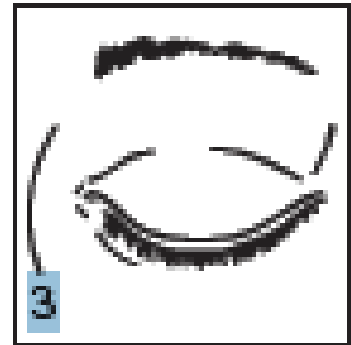
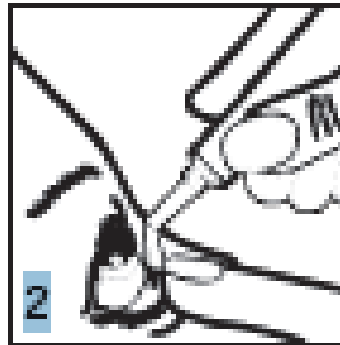
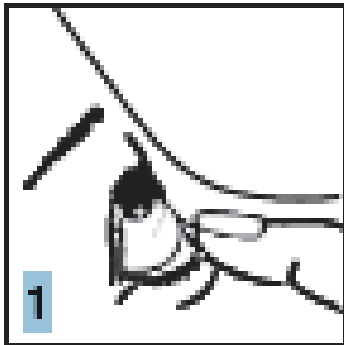
In order to prevent contamination of the ointment, Do not allow the tip of the tube to come into contact with any surface (including the eye itself). Following use, wipe the tube tip with a clean tissue and afterwards, close the tube tightly.

How to use this ointment:

First, wash your hands. Tilt your head back and pull the lower eyelid downwards to form a "pocket" (see Picture 1). Administer the medicine into this "pocket".

Bring the tip of the tube close to the eye. Make sure that the tube tip does not touch the eye, the eyelid and their surroundings. Gently squeeze the tube until a thin ribbon is expelled to the "pocket" (see Picture 2). An amount of 1 cm of ointment is usually sufficient, unless you have received other instructions from the doctor or the pharmacist. Close your eyes gently for 1-2 minutes (see Picture 3).

After using this eye ointment, wash your hands in order to clean them from traces of the medicine. In order to prevent spread of infection, do not use the same tube of medicine in more than one person.



If you applied accidentally an overdose:

Duratears can be used as often as needed, unless your doctor has told you differently.

- If you have applied more Duratears into your eye than necessary, wait a few minutes until the ointment softens, then gently wipe away excess ointment from the lower eyelid. Be careful not to touch the eye with either your fingertip or a tissue. If needed, you can rinse it out of your eye with lukewarm water. Don't put in any more ointment until it's time for your next regular dose.

If you swallowed accidentally the content of the entire tube, no side effects are to be expected; however, it is recommended to refer to a doctor, pharmacist or anti-poison center. If a child accidentally swallowed the medicine, refer to a doctor or to the emergency ward of a hospital immediately and bring the package of the medicine with you.

If you forgot to take this medicine at the designated time, take a dose as soon as you remember, However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not put extra ointment in your eye to make up for the forgotten 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 stop using Duratears

In case you stop treatment, be aware that your symptoms of dry eye(s) may re-occur.

If you have further questions on the use of this medicine, ask your doctor or pharmacist.

4. Side effects:

As with any medicine, use of **Duratears** can cause side effects in some users. Do not be alarmed when reading the list of the side effects. You may not experience any of them.

The following side effects have been seen with DURATEARS. Frequency (not known) cannot be estimated from the available data:

- Effects in the eye: eye pain, eye swelling, itchy eye, eye irritation, abnormal

sensation in the eye, eye redness, blurred vision, eye discomfort, increased tear production

- General side effects: headache

If you get any side effect, or if any of the side effects worsens, or if you suffer from a side effect not listed in the leaflet, consult your doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage

(www.health.gov.il) that directs you to the online form for reporting side effects,

or by entering the link:

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

5. How should the medicine be stored ?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach of children and/or infants to avoid poisoning.

Do not induce vomiting without explicit instruction from the doctor.

- Do not use the medicine after the expiry date (exp. date) that appears on the package.

The expiry date refers to the last day of the same month.

- Store at a temperature range of 15°- 25°C.

- Do not use the medicine for more than a month from the time the tube was first opened.

- Do not store different medicines in the same package.

6. Additional information:

In addition to the active ingredient(s), The medicine also contains: The medicine does not contain active ingredients. The medicine contains: Anhydrous liquid lanolin, Mineral oil, White petrolatum.

What does the medicine look like and what is the content of the package:

A tube containing a white to light yellow, translucent, homogenous ointment.

License holder and its address: Lapidot Medical Import and Marketing Ltd., 8 Hashita St., Caesarea Industrial Zone 38900.

Manufacturer and its address: Alcon-Couvreur, Puurs, Belgium.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 1093324050

Revised in September 2022 according to MOH guidelines