

Patient package insert in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only.

LACROMYCIN

STERILE OPHTHALMIC DROPS

The active ingredient and its concentration:

Gentamycin Sulfate (Equivalent to 0.3% Gentamycin base)

Each 1 ml contains: Gentamycin 3 mg (as sulfate)

For the list of inactive and allergenic ingredients in the preparation, see section 6 - "Further information" and section 2 - "Important information about some ingredients of the medicine".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have any other questions, consult your doctor or pharmacist. This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. What is the medicine intended for?

For treatment of external infections of the eye caused by bacteria susceptible to the medicine.

Therapeutic group: Antibiotics of the aminoglycoside group.

2. Before using the medicine

Do not use the medicine if:

You are allergic to the active ingredient or to any of the additional ingredients that the medicine contains (see section 6 – "Further Information").

Special warnings associated with use of the medicine:

Before treatment with Lacromycin, inform your doctor if:

- You are pregnant (first/last trimester) or breastfeeding.
- You suffer or have suffered from impaired hearing or impaired kidney function.
- You are sensitive to any type of food or medicine.

Extended use can cause development of resistant bacteria including fungal infection.

Drug interactions

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

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, consult your doctor before starting treatment with this medicine.

Important information about some ingredients of the medicine

Lacromycin contains the preservative Benzalkonium Chloride, which can be absorbed by soft contact lenses.

- This preparation should not be used while you wear soft contact lenses.
- The lenses should be removed before using the preparation, and may be replaced no less than 15 minutes after application of the medicine to the eye.

3. How should you use the medicine?

Always use according to your doctor's instructions. Check with your doctor or pharmacist if you are unsure. The dose and treatment regimen will be determined only by your doctor.

Do not exceed the recommended dose. Do not swallow! This medicine is intended for external use only.

Directions for use:

1. In order to prevent contamination, do not let the tip of the bottle touch any surface (including the eye itself). Keep the bottle well closed.
2. The bottle of eye drops may not be full; this is intended to allow better control of the drip rate.
3. How to use the drops: First, wash your hands. Tilt your head back. Using your index finger, pull the lower lid down, to create a "pocket". Drip the medicine into the "pocket" that was created. Gently close your eyes. Do not blink. Keep your eyes closed for 1 to 2 minutes.
4. In addition to the instructions provided above – immediately after instilling the drops into the eye, using your middle finger, press on the inner corner of the eye. Continue to press for 1 to 2 minutes after instilling the drops into the eye. This action helps to prevent absorption of the medicine into the body and thus helps to prevent side effects.
5. Following use of the medicine, wash your hands thoroughly in order to remove any residue of the medicine from them.
6. In order to avoid spreading infection, do not use the medicine bottle for more than one person.

If there is no improvement in your condition within a few days, consult your doctor.
This medicine is to be used at specific time intervals as determined by your doctor.

If you have accidentally taken a higher dose: If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.

If you have forgotten to take the medicine: If you have forgotten to take this medicine on time, take the dose immediately when you remember but on no account should you take a double dosage! Adhere to the treatment regimen as recommended by your doctor. Even if there is an improvement in your health condition, do not stop treatment with this medicine without consulting your doctor.

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

If you have additional questions regarding use of the medicine, consult a doctor or pharmacist.

4. Side effects:

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

Discontinue use of the medicine and refer to your doctor immediately if the following side effects develop:

Stinging, redness and swelling.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, you must consult your doctor.

Reporting side effects:

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects due to 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, should be kept in a closed place out of reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without explicit instruction from a doctor.
- Do not use the medicine after the expiry date (exp. Date) that appears on the box carton and label. The expiry date refers to the last day of that month.
- **Storage conditions:** Do not store above 25°C. Do not freeze.
- Store in the original package. Do not store different medications in the same package.
- Do not use this product for more than 1 month after the bottle is first opened.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Benzalkonium Chloride, Povidone, Purified Water, Sodium Chloride, Sodium Phosphate Dibasic, Sodium Phosphate Monobasic.

What does the medicine look like and what are the contents of the package?

Lacromycin is a preparation of eye drops that comes in a plastic bottle with a dropper that contains 5 ml of a clear, transparent solution.

Name of the manufacturer, registration holder and address: Fischer Pharmaceutical Industries Ltd., 9 Bar Yohai Street, Bnei Brak 5155309 or P.O.B: 39071, Tel Aviv 6139001.

This leaflet was revised in February 2023 in accordance with the Ministry of Health guidelines.

Drug registration number in the National Drug Registry of the Ministry of Health: 509624707.

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