

LIVOSTINE[®], Eye Drops Suspension

Levocabastine (as HCl) 0.5 mg/ml

Inactive and allergenic ingredients in the product - see section 6 "Further Information"

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

This medicine has been prescribed for your treatment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

This medicine is not intended for children under 6 years of age.

1. WHAT IS THE MEDICINE INTENDED FOR?

Livostine Eye Drops is intended for immediate and long-lasting relief of eye symptoms, such as irritation, redness and tearing associated with allergies to grass, pollen, mold, dust and other substances.

Therapeutic group: Antihistamine

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine (see section 6, "Further Information"). If you are not sure, consult a doctor or pharmacist.

Special warnings regarding use of the medicine:

Before treatment with Livostine, tell the doctor if:

- you are pregnant, planning a pregnancy, breastfeeding or are interested in breastfeeding.
- you are suffering, or have suffered in the past, from a kidney disease.
- you wear soft contact lenses. As with all eye drops that contain benzalkonium chloride (a preservative), it is recommended not to wear soft contact lenses when using Livostine Eye Drops.

There is limited experience with use of Livostine in children under 6 years of age. If you have questions regarding use of the medicine in children, refer to a doctor for further information.

The doctor will recommend whether the medicine should be used or not or will recommend adjustment of the dosage or treatment.

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

Pregnancy and breastfeeding

If you are pregnant, or may be pregnant, inform the doctor, who will decide if you can use Livostine.

Do not use Livostine Eye Drops while breastfeeding without first consulting your doctor.

Driving and use of machines

Use of the medicine does not usually affect alertness or concentration. However, if you feel sleepy, care should be taken when driving or operating machinery.

Important information regarding some of the ingredients of the medicine

The product contains 0.15 mg/ml benzalkonium chloride.

As with other eye drops that include this preservative, do not wear soft contact lenses during treatment with Livostine.

3. HOW SHOULD THE MEDICINE BE USED?

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

The usual dosage in adults and children (above 6 years of age) is generally: one drop of Livostine in each eye, twice daily. If the symptoms are very bothersome, you can apply one drop to each eye, 3 or 4 times a day. Do not use Livostine Eye Drops for more than 8 consecutive weeks.

Do not exceed the recommended dose

Do not swallow

This medicine is intended for external use only

Direction for use:

Do not use this product if its package is torn or damaged.

Livostine Eye Drops come as a suspension; therefore, the bottle must be **shaken well** before each use. It may be more comfortable to instill the drops while sitting or lying down.

1. Wash your hands.
2. Shake the bottle well before removing the cap. Before first use of the eye drops, completely remove the ring cover sealing the cap.
3. Tilt your head back as far as you can and look up.
4. Using your index finger, pull the lower eyelid downward to create a sort of "pocket". Bring the tip of the bottle close to the eye. Instill one drop into the "pocket" that is formed. Close your eyes gently. Do not blink or rub your eyes.
5. While your eye is closed, apply slight pressure for a few minutes with your fingers, on the bridge of the nose, to prevent the medicine from draining from the eye.
6. Repeat steps 3-5 for the other eye.



To avoid infection, do not allow the tip of the bottle to touch any surface (including the eye itself). Keep the bottle closed tightly. After using the medicine, wash your hands thoroughly in order to wash off remnants of the medicine. In order to avoid transmitting the infection, the same bottle of medicine shall not be used by more than one person. Continue the treatment until the symptoms improve.

Overdose: Livostine is eye drops intended for use in the eyes only. However, if you accidentally swallowed the medicine, you may feel a bit sleepy. If this happens, drink plenty of water until receiving other instructions from the doctor. If you took an overdose, or if a child accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forget to take the medicine at the required time, take a dose as soon as you remember, and continue treatment as usual. If it is almost time for the next dose, skip the forgotten dose and take the next dose.

Do not use a double dose to compensate for the forgotten dose.

If you missed more than one dose, or if you are not sure what to do, refer to a doctor or pharmacist.

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

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

4. SIDE EFFECTS

As with any medicine, use of Livostine may 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.

Stop using the medicine and refer to a doctor immediately if you notice or suspect a severe allergic reaction, as you may require urgent medical attention. Signs can include: swelling of the face, lips, eyelids, tongue, mouth or throat; wheezing or difficulty swallowing, shortness of breath; rash or hives (urticaria).

If you experience side effects while using the medicine, including the effects listed below, inform a doctor or pharmacist:

- Abnormally fast heartbeats
- Blurred vision
- Slight irritation of the eye, e.g., burning sensation, redness, conjunctivitis, pain, swelling, inflammation of the eyelid, itching, watering of the eyes
- Congestion of blood in the eye
- Slight irritation of the nose, e.g., nasal congestion, nasal discomfort, burning or dry sensation
- Inflammation of the eye (discharge with itching of the eye and crusty eyelids)
- Headache
- Sleepiness
- Nosebleed
- Hives (urticaria – an allergic skin reaction)
- Nausea
- Cough
- Dizziness
- Fatigue
- Throat pain
- Achiness
- Breathing difficulties
- Skin irritation
- Hypersensitivity
- General unwell feeling.

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

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, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by 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 that month.
- Store Livostine Eye Drops at a temperature that does not exceed 25°C.
- Use within one month of first opening the bottle.

6. FURTHER INFORMATION

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

Propylene glycol; Disodium hydrogen phosphate anhydrous; Sodium dihydrogen phosphate monohydrate; Hypromellose 2910 3000 mPa.s; Polysorbate 80; Benzalkonium chloride solution; Disodium edetate; Water for injection.

What the medicine looks like and the contents of the package:

Livostine is a sterile white suspension in a plastic bottle with a dropper. The bottle contains 4 ml.

Registration Holder and address: J-C Health Care Ltd., Kibbutz Shefayim 6099000, Israel.

Manufacturer: Famar S.A., Agiou Dimitriou 63, Alimos 17456, Athens, Greece.

Revised in October 2023 according to MOH guidelines.

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

141 53 27673