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

This medicine is dispensed with a doctor's prescription only

Levodesa

Eye drops

Active ingredients
Each 1 ml contains:

dexamethasone (as sodium phosphate)	1 mg
levofloxacin (as hemihydrate)	5 mg

Inactive ingredients and allergens - see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

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

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

1. What is this medicine intended for?

Levodesa is used to prevent and treat inflammation and prevent infection of the eye after cataract surgery in adults.

Therapeutic group:
Levodesa contains two active ingredients:

- dexamethasone - a corticosteroid that has anti-inflammatory properties (to treat symptoms like pain, heat, swelling and redness).
- levofloxacin - an antibiotic of the fluoroquinolone family (sometimes shortened to "quinolones"). Levofloxacin works by killing certain bacteria that can cause infections.

2. Before using the medicine

Do not use this medicine if:

- you are sensitive (allergic) to dexamethasone (or other corticosteroids), levofloxacin (or other quinolones) or to any of the other ingredients in this medicine. For the list of the inactive ingredients, see section 6.
- you are suffering from an eye infection that is not being treated with medicine, including a viral infection (like herpes simplex, keratitis or varicella), fungal infection

and tuberculosis of the eye. You could have an infection if you have a sticky discharge from your eye or a red eye that has not been checked by a doctor.

Special warnings about using this medicine
Before using Levodesa, tell your doctor if:

- you are using any other antibiotic, including oral antibiotics. As with other anti-infectives, prolonged use may cause antibiotic resistance that leads to overgrowth of pathogenic microorganisms.
- you suffer from high pressure in the eye or if you have already had high pressure in the eye after using a steroid medicine administered to the eye. You are at risk of having this again if you use Levodesa. If you suffer from high pressure in the eye, tell your doctor.
- you have glaucoma.
- you have visual disturbances or blurred vision.
- you are using ocular NSAIDs (nonsteroidal anti-inflammatory drugs). See section 'Interactions with other medicines'.
- you have a disorder causing a thinning of the eye tissues because prolonged steroid treatments may cause further thinning and perforation.
- you are diabetic.

Using contact lenses
After cataract surgery, you should not wear contact lenses for the whole period of treatment with Levodesa.
Benzalkonium chloride may be absorbed by soft contact lenses and discolour them.

Children and adolescents
Levodesa is not intended for use in children and adolescents below the age of 18 due to a lack of information on safety and efficacy of the use of this medicine in this age group.

Interactions with other medicines
If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist. Particularly if you:

- are using any other eye drops or eye ointments before you start to use Levodesa (see section 3 – 'How to use this medicine').
- are using ocular NSAIDs (used against pain and inflammation in the eye) like ketorolac, diclofenac, bromfenac and nepafenac. Simultaneous use of ocular steroids and ocular NSAIDs may increase the risk of healing problems in your eye.

- you are using ritonavir or cobicistat (used in HIV treatment), as these may increase the amount of dexamethasone in the blood.
- you are using probenecid (to treat gout), cimetidine (to treat stomach ulcer) and cyclosporin (to prevent transplant rejection) as they may change absorption and metabolism of levofloxacin.

Pregnancy and breast-feeding
The information about the use of dexamethasone or levofloxacin during pregnancy is limited. Prolonged or repeated use of corticosteroids during pregnancy may affect your unborn baby.
Furthermore, corticosteroids administered systemically and levofloxacin are passed into breast milk, although the information about the effect on the baby is limited.
Since it is not possible to rule out systemic exposure to corticosteroids after administration to the eye, if you are pregnant or breast-feeding, think you may be pregnant or are planning to become pregnant, consult your doctor or pharmacist before using this medicine. Use of Levodesa during pregnancy or breast-feeding is not recommended.

Driving and using machines
You may experience short-term blurred vision after using this medicine. If you experience blurred vision, do not drive or operate machines.

Important information about some of this medicine's ingredients

Levodesa contains 4.01 mg phosphates per ml, which is equivalent to 0.12 mg per drop.
If you suffer from severe damage to the clear layer at the front of the eye (the cornea), phosphate may cause in very rare cases cloudy patches on the cornea due to calcium build-up during treatment. Contact your doctor who may prescribe you a phosphate-free treatment.

Levodesa contains 0.05 mg benzalkonium chloride per ml, which is equivalent to 0.0015 mg per drop. Benzalkonium chloride may cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel a strange eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

3. How to use this medicine?
Always use according to your doctor's instructions.
Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.
The recommended dose is usually:
One drop in the affected eye every 6 hours. The maximum dose is 4 drops per day.

Do not exceed the recommended dose.

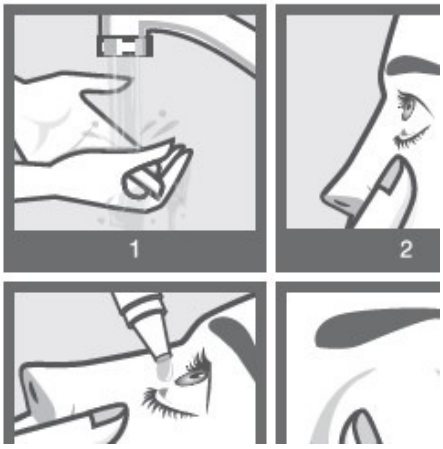
When to take the medicine and for how long
The usual total treatment course with Levodesa is 7 days, followed, if deemed necessary by your doctor, by another 7 days of steroid eye drops. Use the drops for the length of time your doctor instructs you to.

Do not swallow. This medicine is intended for external use only.

If you are using another type of eye drops or ointment, wait at least 15 minutes between use of Levodesa and the other type of medicine. If you are using an eye ointment, it should be used last.

Instructions for use:
If possible, ask someone else to apply the drops for you. Ask them to read these instructions with you before applying the drops.

1. Wash your hands carefully (Figure 1).
2. Open the bottle. **Remove the loose collar from the cap when the bottle is first opened.** Take special care that the tip of the dropper does not touch your eye, the skin around your eye or your fingers.
3. Twist off the bottle cap. Hold the bottle pointing down, between your thumb and fingers.
4. Pull down your lower eyelid with a finger, until there is a “pocket” between your eye and eyelid. The drop will go in here (Figure 2).
5. Tilt your head back and bring the bottle tip close to the eye and squeeze the bottle gently in the middle in order to allow only one drop to fall into the “pocket” created (Figure 3). Note that there might be a few seconds delay between squeezing and the drop coming out. Do not squeeze hard.
6. After putting the drop into your eye, press a finger into the corner of your eye by the nose. This helps to stop the medicine from being absorbed into the body (Figure 4).



If a drop misses your eye, try again. Put the bottle cap firmly back on immediately after use.

If you have accidentally used a higher dose
If you use a higher dose of Levodesa than required, you should rinse your eye with lukewarm water.
If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to use this medicine
If you forget to use this medicine, use it as soon as you remember. Do not take a double dose to make up for a forgotten dose.
Adhere to the treatment as recommended by your doctor.

If you stop using this medicine
Do not stop using Levodesa without first consulting your doctor.

Do not take medicines in the dark! Check the label and dose <u>every time</u> you take medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects
As with any medicine, using Levodesa may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them. Most side effects are not serious and affect only the eye.

In very rare cases, this medicine can cause severe allergic reactions (anaphylactic reactions), accompanied by swelling of the throat, tightness in the throat and airways and breathing difficulties. **Stop using Levodesa and seek medical assistance immediately if any of these symptoms occurs.**
Tendon swelling and rupture have happened in people taking oral or intravenous fluoroquinolones, particularly in the elderly and in those treated concurrently with corticosteroids. **Stop using Levodesa** if you develop pain or swelling of the tendons (tendinitis).

Other side effects that may affect your eyes
<u>Very common side effects - affect more than one in ten users:</u>
high pressure in the eye.

<u>Common side effects - affect 1-10 in 100 users:</u>
discomfort, stinging or irritation, burning, itching in the eye, blurred or decreased vision, mucus in the eye.

Uncommon side effects – affect 1-10 in 1,000 users:
corneal healing which takes longer than expected, eye infections, abnormal sensation in the eyes, increased tearing, dry and tired eye, pain in the eye, brighter vision, swelling or redness (bloodshot eyes) of the front covering of the eye (conjunctivae), swelling or redness of the eyelid, sensitivity to light, sticky eyelids.

Very rare side effects – affect up to one in 10,000 users:
increase in pupil size, drooping eyelids, appearance of calcium on the surface of the eye (calcification of cornea), tears and a sandy sensation in your eye (crystalline keratopathy), change in the thickness of the surface of the eye, ulcer on the surface of the eye, small holes on the surface of the eye (perforation of the cornea), swelling of the surface of the eye (corneal oedema), inflammation of the eye which causes pain and redness (uveitis).

Other side effects that may affect other areas of your body
Uncommon side effects – affect 1-10 in 1,000 users:
headache, alteration of the taste, pruritus, stuffed or runny nose.

Rare side effects affect 1-10 in 10,000 users:
allergic reactions such as skin rash.

Very rare side effects – affect up to one in 10,000 users:
facial swelling.

Side effects of unknown frequency (the frequency of these effects has not been established yet):
reduction of adrenal gland function, which could be shown by low blood sugar levels, dehydration, weight loss and feeling confused about where you are.
Hormone problems: growth of extra body hair (particularly in women), muscle weakness and wasting, purple stretch marks on body skin, increased blood pressure, irregular or missing periods, changes in the levels of protein and calcium in your body, stunted growth in children and teenagers, swelling and weight gain of the body and face (Cushing's syndrome).
If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects
You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il), which opens an online form for reporting side effects, or you can also use this link:
https://sideeffects.health.gov.il

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by your doctor.

Do not use the medicine after the expiry date (exp. date) which is stated on the package/bottle. The expiry date refers to the last day of that month.

Storage conditions

- Store at a temperature that does not exceed 25˚C.
- Do not use this medicine if you notice that the plastic film around the cap and neck is missing or broken.
- Keep the bottle tightly closed.
- You must throw away the bottle 28 days after you opened it to prevent infections.
- Do not throw away medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredients, this medicine also contains:

sodium citrate, disodium phosphate dodecahydrate, sodium dihydrogen phosphate, benzalkonium chloride, sodium hydroxide, hydrochloric acid, water for injection.

What the medicine looks like and contents of the pack:

A clear, greenish-yellow solution.

Each pack contains a white plastic bottle with a dropper.

Each bottle contains 5 ml of solution.

Registration holder's name and address:

Taro International Ltd., 14 Hakitor Street, Haifa Bay 2624761.

Manufacturer's name and address:

NTC S.r.l

Via Luigi Razza n. 3, Milan, Italy

Approved in January 2024.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 174-83-36730-99