The format of this leaflet was determined by the Ministry of Health, and its content was checked and approved by it in August 2013.

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Maxidex®
Ophthalmic Suspension

Composition: Dexamethasone 1 mg/ml

Read this package insert carefully in its entirety before using the 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 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?

Therapeutic activity: Treatment of steroid-responsive ocular inflammations.

Therapeutic group: Corticosteroid, anti-inflammatory.

2. BEFORE USING THE MEDICINE:

☒ Do not use the medicine if:

- you have a known sensitivity to any of the ingredients of the medicine.
- you suffer from herpes simplex in the eye, from an ocular fungal or bacterial infection, from an ocular viral disease, from ocular tuberculosis (even if you have suffered in the past) or from untreated ocular purulent infections.
- after removal of a foreign body from the eye that did not cause complication.
- do not take this preparation to relieve undefined redness.

Before the treatment with Maxidex, tell the doctor if:

- if you are suffering, or have suffered in the past, from impaired function of: the eyes, such as glaucoma, cataract, ocular nerve injury, vision impairment, other ocular infections.
- if you suffer from diabetes.

Warnings:

- Prolonged use may cause corneal infection.
- When the treatment period exceeds 10 days, intraocular pressure measurements must be carried out; glaucoma patients should have their intraocular pressure measured on a weekly basis.
- If you suffer from a disease that causes thinning of the ocular tissues (cornea or sclera), use of Maxidex may cause perforation of the eyeball.
- Upon prolonged use or use of high dosages - systemic side effects associated with steroids may occur.
- Use of Maxidex is not effective in cases of Sjogren's syndrome, characterized by reduced secretion of tears and saliva.
- Do not stop treatment abruptly without consulting the doctor.

! If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. It is especially important to inform the doctor or the pharmacist if you are taking:

- Eye drops given to dilate the pupils (which contain atropine or other anticholinergic agents). Together with Maxidex, these medicines may cause increased intraocular pressure.
- If the patient is using other eye drops, wait at least 15 minutes between instillations.

! Pregnancy and breastfeeding:

Pregnancy: Consult a doctor before commencing treatment if you are pregnant, or planning to become pregnant. Use of Maxidex during pregnancy requires caution.

Breastfeeding: Consult a doctor before commencing treatment if you are breastfeeding. Steroids are secreted into breast milk. When necessary, the doctor may recommend short-term treatment (1-2 weeks) with Maxidex. Stop breastfeeding in cases of prolonged use of Maxidex or use of high dosages of the preparation.

! Driving and use of machines:

Use of this medicine may cause blurred vision and therefore requires that caution be exercised when riding a car, operating machinery and the like.

! Important information regarding some of the ingredients of the medicine:

- This preparation contains the benzalkonium chloride preservative, which may be absorbed by soft contact lenses. Do not use this preparation when you are wearing soft contact lenses. Remove the lenses before using this preparation and replace them after at least 15 minutes have elapsed from instilling the medicine into the eye.
- The doctor may even recommend that you avoid wearing contact lenses throughout the course of treatment.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure.

Dosage: The dosage is according to the doctor's instructions only. Do not exceed the recommended dose. This medicine is not usually intended for children below the age of two. If there is no improvement in your condition within 5-7 days, refer to a doctor.

Do not exceed the recommended dose.

Attention: This medicine is intended for external use only.

Shake the bottle well before use.

In order to prevent contamination, do not allow the tip of the bottle to touch any surface (including the eye itself). Keep the bottle closed tightly.

The bottle of drops may not be full; this is to allow for better control of the drip rate.

Wash your hands. Tilt your head back. With the aid of the forefinger, pull the lower eyelid downward, to form a "pocket". Instill the medicine into the "pocket" formed. Close your eyes gently. Do not blink. Keep your eyes closed for 1 to 2 minutes.

In addition to the instructions above, immediately after instilling the drops into the eye, press with your middle finger on the inner corner of the eye. Continue pressing for 1 to 2 minutes after applying to the eye. This action helps prevent absorption of the medicine into the body and thereby helps prevent side effects.

After using the medicine, wash your hands thoroughly to clean them of remnants of the medicine.

In order to prevent spread of the infection, do not use the same bottle of medicine for more than one person.

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 this medicine, use it when you remember. However, if it is almost time for the next dose, skip the forgotten dose and continue taking the medicine as usual. Do not take a double dose.

Adhere to the treatment regimen as recommended by the doctor.

Even if there is an improvement in your health condition, do not stop treatment with this medicine without consulting the 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 any further questions regarding use of this medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS:

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

Side effects requiring special attention:

Decreased vision, ocular infection, eye pain, gradual blurring or loss of vision, nausea, vomiting (rare): consult a doctor immediately.

Mild and temporary blurring of vision after using the preparation, burning, redness, tearing - refer to the attending doctor.

Side effects occurring infrequently: increased intraocular pressure.

Side effects occurring rarely: local irritation, local allergic reactions, glaucoma accompanied by optic nerve injury, cataract, development of ocular infections or exacerbation of preexisting infections.

Side effects occurring very rarely: perforation of the eye.

If any of these side effects worsen, or if you suffer from any side effect not listed in this leaflet, consult with the doctor.

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 carton/label. The expiry date refers to the last day of that month.
- Store below 25°C and in an upright position.
- Do not use the medicine for more than one month (28 days) after first opening the bottle.

6. FURTHER INFORMATION:

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

Disodium phosphate anhydrous, polysorbate 80, disodium edetate, sodium chloride, citric acid monohydrate and/or sodium hydroxide, benzalkonium chloride, hydroxypropyl methylcellulose, purified water.

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

A bottle which contains 5 ml of white-yellowish fluid.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
128 87 29422

Manufacturer: Alcon-Couvreur, Puurs, Belgium.

License holder: Lapidot Medical Import and Marketing Ltd., 8 Hashita St., Industrial Zone, Caesarea, 3088900.