The format of this leaflet was determined by the Ministry of Health and its content was checked and approved by it

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

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

Voltaren Ophtha Eye Drops

Composition: Diclofenac sodium 1 mg/ml

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 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 group: Non-steroidal anti-inflammatories.

Therapeutic activity: For treatment of post-operative eye inflammation after cataract surgery. For relief of ocular pain and discomfort associated with corneal epithelial defects after laser surgery or accidental trauma to the eye.

2. BEFORE USING THE MEDICINE:

☒ Do not use this medicine:

- if you have a known sensitivity to the active ingredient or to any ingredient in the preparation (see section 6).
- in patients in whom asthma attacks, urticaria, or acute rhinitis are caused by use of acetylsalicylic acid or by other medicines which inhibit prostaglandin synthesis.
- if you are sensitive to acetylsalicylic acid, to phenylacetic acid derivatives or to other non-steroidal anti-inflammatories, there is a chance of sensitivity to this preparation, and vice versa.
- if you are in the third trimester of pregnancy.

Before treatment with Voltaren Ophtha, tell the doctor if:

- you are pregnant or breastfeeding.
- you are suffering from impaired blood clotting.

Special warnings regarding use of the medicine:

- The anti-inflammatory activity of **Voltaren Ophtha** may mask the onset and/or progression of ophthalmic infections. In case of infection or risk of infection, appropriate therapy should be given concurrently with **Voltaren Ophtha**.
- Use of topical non-steroidal anti-inflammatories may prolong bleeding time. Use precautionary measures when using **Voltaren Ophtha** in patients taking other medicines which may prolong bleeding time (e.g., anticoagulants), in patients with high risk of bleeding or when using **Voltaren Ophtha** during surgery.
- Caution must be exercised when using diclofenac and topical steroids concomitantly.
- Do not wear soft contact lenses when instilling **Voltaren Ophtha**. Remove contact lenses before applying the preparation, and do not reinsert them less than 15 minutes after use.

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

- Medicines from the following groups: steroids, aspirin, non-steroidal anti-inflammatory drugs, other medicines for ophthalmic treatment, anticoagulants.
- Concomitant use of topical non-steroidal anti-inflammatories such as diclofenac and topical steroids in patients suffering from a significant preexisting corneal inflammation may increase the chance of corneal complications; therefore, caution should be exercised.
- If indicated, **Voltaren Ophtha** can be used concomitantly with eye drops that contain antibiotics or beta-blockers.

▯ Pregnancy and breastfeeding:

Do not use this preparation if you are in the third trimester of pregnancy.

Do not use the preparation without consulting a doctor before starting treatment if you are pregnant or breastfeeding.

▯ Elderly:

There is no indication that the dosage needs to be adjusted for the elderly.

▯ Children:

This medicine is not usually intended for children and infants.

▯ Driving and use of machines:

Use of this medicine may cause blurred vision and therefore, caution should be exercised when driving a car, operating machines and the like.

▯ Important information regarding some of the ingredients in this medicine:

The preparation contains the preservative benzalkonium chloride which may cause eye irritation and is known to stain soft contact lenses.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions.

Check with the doctor or pharmacist if you are unsure.

The dosage and treatment regimen will be determined by the doctor only.

Do not exceed the recommended dose.

Note: Do not swallow! This medicine is intended for use in the eyes only. Eye drops are not intended for injection.

The solution remains sterile until the bottle is first opened. Avoid touching the eye or any other surface with the tip of the bottle, as this may contaminate the solution.

Close the bottle immediately after use.

If an additional ophthalmic preparation is to be used, wait 5 minutes between use of **Voltaren Ophtha** and use of the other preparation.

After instilling **Voltaren Ophtha**, block the nasolacrimal duct or close your eyes for 5 minutes to reduce systemic absorption.

If you administered an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

Adhere to the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with this medicine without consulting 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 this medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS:

As with any medicine, use of **Voltaren Ophtha** 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.

Effects which require special attention: Eye pain, blurred vision, abnormal sensitivity to light (signs of keratitis), usually after frequent use of the preparation.

A side effect that occurs frequently is transient mild to moderate eye irritation.

Side effects that occur infrequently are eye pain, eye pruritus, red eyes and blurred vision immediately after instilling the drops into the eye, nausea, vomiting.

Side effects which occur rarely: In patients with risk factors for corneal disorders, such as use of corticosteroids, or those who suffer from diseases such as infections or rheumatoid arthritis, concomitant use of diclofenac was associated with a feeling of something in the eye, ulcerative keratitis, corneal thinning, severe eye pain, deterioration of vision, fluid accumulation in the cornea. Most of the patients used the preparation for a long period of time.

Shortness of breath, exacerbation of asthma, allergic reactions, such as red eyes, discharge from the eye with pruritus, redness and swelling (signs of allergic conjunctivitis), red eyelids, eye allergy, swelling of the eyelid, eyelid pruritus, urticaria, rash, skin erythema, pruritus, hypersensitivity, cough and rhinitis - refer to the doctor. Photosensitivity, delayed wound healing.

If any of the side effects worsen, or if you suffer from a side effect not mentioned in this 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://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach of children and/or infants in order 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.
- After first opening, can be used within 1 month.

6. FURTHER INFORMATION:

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

Benzalkonium chloride, Disodium edetate, Hydroxypropyl gamma-cyclodextrin, Hydrochloric acid, Propylene glycol, Trometamol, Tyloxapol, Water for injections.

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

A bottle that contains 5 ml of a clear, colorless and odorless liquid, free of visible particles.

Registration holder: Novartis Israel Ltd., 36 Shacham Street, Petach-Tikva.

Manufacturer: ExcelVision, France for Novartis Pharma AG, Basel, Switzerland.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
065 65 26375

This leaflet was checked and approved by the Ministry of Health in May 2013

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