

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

This medicine can be sold with a doctor's prescription only

## **Dicloftil 0.1% Eye Drops**

**Single use unit**  
**No preservative**

Active ingredient and its concentration:

Each 1 ml contains:

Diclofenac Sodium 1 mg

For list of excipients, please see section 6.

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

This medicine has been prescribed for your illness. Do not pass it on to others. It may harm them, even if you think that their illness is the same as yours.

The use of Dicloftil 0.1% is prohibited in children below 14 years of age since there are no sufficient efficacy and safety data available in this age group.

### **1. What is the medicine used for?**

- For the treatment of eye inflammation following cataract extraction surgery.
- Relief of ocular pain and discomfort associated with corneal epithelial defects following laser surgery or accidental trauma in the eye.

**Therapeutic group:** Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

### **2. Before you take the medicine:**

<b>Do not use the medicine if:</b>
<ul style="list-style-type: none"><li>• You are hypersensitive (allergic) to the active ingredient (diclofenac sodium), to any of the other ingredients of this medicine or to other non-steroidal anti-inflammatory drugs (aspirin, indomethacin etc.).</li><li>• You have experienced an asthma attack, urticaria or acute rhinitis following administration of aspirin or other prostaglandin-synthesis inhibitor drugs in the past.</li><li>• You are below the age 14.</li></ul>



### **Special warnings about the use of this medicine:**

- Do not wear soft contact lenses during treatment. Contact lenses should be removed before use of this product and should not be worn back before 15 minutes have passed after use.
- In patients with increased risk of corneal disorders, e.g. during use of steroids and in

patients with concomitant diseases like rheumatoid arthritis, the use of diclofenac, the active ingredient in the medicine, was associated (in rare cases) with the appearance of corneal ulcers, corneal thinning, punctate keratopathy, corneal disorders and corneal oedema. Most of these patients were treated for a very long period.

- In the presence of inflammation or if there is a risk of inflammation as a result of bacterial infection, an appropriate therapy (antibiotic) should be given concomitantly with Dicloftil.
- In case of administration with other eye drops, in order to improve absorption, there should be an interval of at least 5 minutes between the application of Dicloftil and the other eye drops.

**Before taking Dicloftil tell your doctor if:**

- You suffer from impaired function of the blood system.
- You are pregnant or breastfeeding (see section "Pregnancy and breastfeeding").
- You are sensitive to any type of food or medicine.

**Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including non-prescription drugs and nutrition supplements.**

Especially inform your doctor or pharmacist if you are taking:

- Aspirin
- Other medicines for ocular treatment
- Concomitant use of topical non-steroidal anti-inflammatory drugs (such as diclofenac) and topical steroids in patients with significant corneal inflammation could increase the risk of developing corneal complications
- Anticoagulants

**Pregnancy and breastfeeding:**

There is not enough information regarding the use of Dicloftil during pregnancy and breastfeeding.

For this reason, the use during pregnancy and breastfeeding is not recommended, with the exception of cases where the physician has carefully evaluated the risk/benefit ratio of the therapy.

If you are pregnant or breastfeeding consult your doctor before using this medicine.

**Driving and use of machinery:**

Use of this medicine can cause blurred vision. If you are affected, do not drive a car or operate dangerous machinery.

Patients with scotoma - should not drive a car or operate machines.

**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.

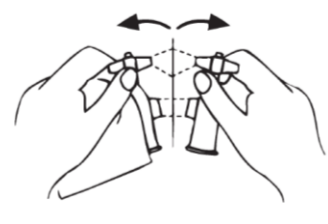
**Do not exceed the recommended dose.**

- Do not swallow.
- For external use only.

**Directions for use of this medicine – general instructions:**

- How to use the drops:

- First, wash your hands thoroughly.
- Open the aluminum sachet and separate one single use container. Open the top of the container with a circular motion.



- Bend your head backwards or lie on a bed and with your index finger, pull down the lower eye lid, to create a "pocket".
- Instill a drop into this "pocket" by gently squeezing the container.
- Close your eyes gently. Do not blink. Keep your eyes closed for 1-2 minutes.
- Immediately after instilling the drop into the eye, using the middle finger press on the inner corner of the eye. Keep pressing 1-2 minutes after instilling into the eye. This helps avoid absorption of the drug into the body and thus helps prevent side effects.
- After the use of this medicine, wash your hands thoroughly in order to clean them from any remaining medicine.
- After the first opening of the single use container, you should use the medicine and discard the remaining quantity.
- In order to avoid spreading the infection, do not use the same container of medicine for more than one person.

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

**If you forget to take this medicine** at the specified time, take it as soon as you remember, but never take two doses together!

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

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

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

#### **4. Side effects:**

Like all medicines, Dicloftil can cause side effects, although not everybody gets them. Do not be alarmed while reading the list of side effects, you may not suffer from any of them.

**Refer to your doctor as soon as possible if:**

- You suffer from hypersensitivity reactions such as: itch and redness, inflammation of the cornea, ocular pain, blurred vision, hypersensitivity to light (signs of corneal inflammation), usually after frequent use of this product.

**Additional side effects:****Appear commonly:**

- Light to moderate transitory burning sensation and scotoma immediately after use of the eye drops.

**Appear uncommonly:**

- Ocular pain, blurred vision immediately after use of the eye drops.

**Appear rarely:**

- Hypersensitivity reactions such as itch, red eyes and photosensitivity.
- Cases of punctate keratopathy and corneal disorders were observed following frequent use.
- Dyspnea (shortness of breath) and asthma exacerbation.
- Thinning and ulceration of the cornea.

Moreover, the following allergic reactions were reported: conjunctival hyperemia, allergic conjunctivitis, palpebral erythema, ocular allergy, palpebral oedema, palpebral itch, urticaria, rash, eczema, cough or allergic rhinitis.

If any of the side effects worsens, or if you experience side effects not mentioned in this leaflet, consult your doctor.

**5. How to store the medicine**

- Avoid poisoning! This medicine, and all other medicines, must be stored in a safe place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by your doctor!
- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
- Do not store at a temperature above 25°C.
- Use Dicloftil 0.1% drops within 28 days from first opening of the aluminum sachet containing the single use containers.
- Use immediately after opening of the single use containers and discard even if solution remained in the container.
- Medicines should not be disposed of via household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**6. Additional information****In addition to the active ingredient, this medicine also contains:**

Arginine, Boric Acid, Borax, Povidone K25, Macrogolglycerol ricinoleate, Disodium edetate, Water for injection.

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

Each pack contains 30 containers of 0.5 ml eye drop solution for single use.

**Registration holder:** BioAvenir Ltd., Kibbutz Glil-Yam 46905.

**Manufacturer:** Farmigea, Italy

**Drug registration number at the national medicines registry of the Ministry of Health:** 138 87 31465 00

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

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