

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

The medicine is dispensed with a doctor's prescription only

Dicloftil 0.1% eye drops

Single dose container Preservative-free

The active ingredient and its concentration:
Each 1 ml contains 1 mg diclofenac sodium.

Inactive ingredients and allergens: see section 2 "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 for you to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to 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 this medicine intended 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 using this medicine:

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient (diclofenac sodium), to any of the other ingredients of this medicine (listed in section 6) or to other non-steroidal anti-inflammatory drugs (aspirin (acetylsalicylic acid), indomethacin etc.).
- You have had an asthma attack, urticaria or acute rhinitis after taking aspirin (acetylsalicylic acid) or other prostaglandin-synthetase inhibitor drugs in the past.
- You are under the age of 14.

Special warnings about using this medicine

- Do not wear soft contact lenses during treatment with this medicine. Contact lenses should be removed before use of this medicine and should not be worn back before 15 minutes have passed after use.
- In patients who have an increased risk of disease of the cornea (transparent front part of the eye), for example during the use of steroids (medicines used to treat a large number of conditions that cause inflammation), and in patients with concomitant diseases such as rheumatoid arthritis (chronic inflammatory disease affecting the joints), the use of diclofenac, the active ingredient in the medicine, has been associated (in rare cases) with the appearance of ulcerative keratitis (inflammation and injury of the cornea) or thinning of the cornea, spots on the cornea, punctate keratitis (another form of inflammation of the cornea), corneal disorders, defects in the corneal epithelium (i.e., the most superficial layer of the cornea), and edema (swelling) of the cornea. Most patients who presented with these complications were treated for a very long period of time.
- 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.
- Nonsteroidal anti-inflammatory drugs (NSAIDs) such as diclofenac should be administered with caution in conjunction with topical (local use) steroids.

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.

Children and adolescents

Do not administer this medicine in children and adolescents younger than 14 years of age (see "Do not use Dicloftil").

Drug interactions

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

- Aspirin.
- Other medicines for ocular treatment. Wait at least 5 minutes before using another medicine.
- Concomitant use of topical nonsteroidal anti-inflammatory drugs (NSAIDs) (such as diclofenac) and topical steroids in patients with significant pre-existing corneal inflammation may increase the risk of developing corneal damage, so such use should be done with caution.
- Anticoagulants.

Pregnancy, breastfeeding, and fertility

Pregnancy

There is no experience with the use of Dicloftil during pregnancy, so you should not use this medicine in the first and second trimesters of pregnancy unless your doctor thinks it is necessary.

In the last trimester, you should not use Dicloftil because of the increased risk of side effects for you and your unborn baby.

Breastfeeding

It is not recommended to use this medication during breastfeeding unless the expected benefits outweigh the potential risks.

Fertility

This medicine contains boron and may affect your fertility in the future. If you are pregnant, talk to your doctor before taking this medicine as it contains boron which may be harmful to your baby.

Driving and using machines

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

Patients with scotomas (serious vision problems) should refrain from driving motor vehicles or operating machinery.

Important information about some of this medicine's ingredients

Dicloftil contains boric acid

This medicine contains boron and may affect fertility in the future.

If you are pregnant, talk to your doctor before taking this medicine because it contains boron that may be harmful to your baby.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions.

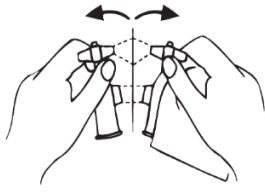
Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine. The recommended dose is 1 drop in the affected eye four times a day, or as directed by your doctor.

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 envelope 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 eyelid, 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 medicine 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 accidentally taken a higher dose, or if a child has accidentally swallowed the medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine at the scheduled time, do not take a double dose. Take the next dose at the usual time and consult your doctor. Adhere to the treatment as recommended by your doctor. Even if your health improves, do not stop taking this medicine without consulting your doctor.

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

Use in children and adolescents under 14 years of age:

Insufficient data are available on the effectiveness and safety in children and adolescents under 14 years of age.

If you have any questions about the use of this medication, ask your doctor or pharmacist.

4. Side effects

Like with all medicines, Dicloftil may cause side effects in some users. 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 medicine.

Additional side effects associated with the use of eye drops containing diclofenac:

- mild to moderate transient burning sensation and/or scotomas (serious vision problems) immediately after using eye drops;
- eye pain and blurred vision immediately after use of the eye drops.

Rare side effects (may affect up to 1 in 1,000 people):

- reactions of excessive sensitivity, such as itching and red eyes;
- excessive sensitivity to sunlight (photosensitivity);
- labored breathing (dyspnea) and worsening of asthma;
- thinning and ulcers (lesions) of the cornea.

Side effects with unknown frequency (frequency cannot be defined based on available data):

- redness of the eye (conjunctival hyperemia), inflammation of the membrane lining the white part of the eye and the inner surface of the eyelids (allergic conjunctivitis), reddened and swollen eyelids (eyelid erythema), eye allergy, swollen eyelids (eyelid edema), itching of the eyelids;
- allergic skin reaction (urticaria), change in skin color and appearance associated with skin irritation or swelling (rash), inflammatory skin reaction (eczema), skin irritation (erythema), itching, excessive allergic-type sensitivity to one or more substances (hypersensitivity);
- cough, cold of allergic nature (rhinitis);
- disorders and inflammation of the cornea (punctate keratitis, ulcerative keratitis, epithelial defects, corneal edema) normally after frequent use of the eye drops;
- burning sensation in the eyes.

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.

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

<https://sideeffects.health.gov.il>

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.
- Do not dispose of any medication in sewage or household waste. Ask your pharmacist how to dispose of medicines you no longer use. This will help 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:

The contents of the package are 30 single-dose 0.5 ml containers.

Registration holder's name and address: BioAvenir Ltd., 1 David Hamelech St., Herzelia Pituach 4666101.

Manufacturer's name and address: Farmigea, Pisa, Italy.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 138 87 31465 00

Revised in April 2022 according to MOH guidelines.