

Package leaflet: Information for the patient

DIFENASOL 0.1 %, eye drops, solution

Diclofenac as sodium diclofenac,

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet?

1. What DIFENASOL is and what it is used for ?
2. What you need to know before you take DIFENASOL ?
3. How to take DIFENASOL ?
4. Possible side effects
5. How to store DIFENASOL ?
6. Contents of the pack and other information

1. What DIFENASOL is and what it is used for?

This medicine contains a non-steroidal anti-inflammatory drug (NSAID) for ocular use.

It is used for to treat the

- external and anterior segment non-infectious inflammatory reactions of the eye,
- postoperative inflammation,
- inhibition of miosis in cataract surgery.

2. What you need to know before you take DIFENASOL ?

Do not take DIFENASOL:

- if you are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6).
- history of allergy or asthma started by the intake of these eye drops or of a similar medicine, such as aspirin and other NSAIDs.
- more than five months pregnancy (24 weeks of absence of menstruation)
- wearing of soft contact lenses.

Warnings and precautions

Talk to your doctor or pharmacist before taking DIFENASOL.

The administration of these eye drops may result in attacks of asthma, especially in some patients with an allergy to aspirin or to a NSAID.

In case of hypersensitivity reactions or signs of allergy to that medicine, especially attack of asthma or sudden face and neck swelling, discontinue the treatment and contact your doctor or the emergency services immediately.

Before using this medicine, inform your doctor in case of asthma combined with a chronic rhinitis, a chronic sinusitis and/or nasal polyposis.

An acute ocular infection may be masked by the topical use of anti-inflammatory drug. NSAIDs do not have any antimicrobial properties. In case of ocular infection, their use with one/some anti-infectious drugs should be done carefully.

The concomitant use of topical NSAIDs and topical corticoids (as dexamethasone) may increase the risk of problems during recovery.

NSAIDs may delay the cornea healing. Topical corticosteroids are known to slow down or delay healing. The concomitant use of NSAIDs and topical corticoids may increase the risk of problems during healing.

If you are predisposed to bleeding or you have an anti-coagulant treatment (medicines to thin the blood).

In case of high dose and prolonged use, the use of topical NSAIDs may result in keratitis.

Other medicines and DIFENASOL

No significant interaction arising from local application of DIFENASOL.

Pregnancy and breast-feeding

First trimester, it is preferable not to use this medicine during the first 12 weeks of absence of menstruation. If you realize that you are pregnant while under treatment, please consult your doctor, who is the only person able to judge the necessity to follow the treatment.

From 2.5 to 5 complete months (between 12 and 24 weeks of absence of menstruation), this medicine is to be used only under a doctor's advice and for a short period of time.

After 5 complete months (24 weeks of absence of menstruation), do not use this medicine, because it can have serious consequences on your child, especially cardio-pulmonary and renal, even after one application.

If you have taken this medicine when you are more than five months pregnant, talk to your obstetrical gynaecologist for a suitable monitoring.

This medicine can be used during breast-feeding.

Driving and using machines

You may briefly experience a visual discomfort after introducing DIFENASOL. Wait until you have recovered normal vision before driving a vehicle or using dangerous machines.

DIFENASOL contains benzalkonium chloride, this medicine may cause eye irritation. Avoid contact with soft contact lenses, remove contact lenses prior to application and wait at least 15 minutes before reinsertion. Benzalkonium chloride is known to discolour soft contact lenses.

3. How to use DIFENASOL

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Wash hands thoroughly before use.

Avoid touching the eyes or eyelids with the tip of the bottle.



1. With the spike: tighten the cap on the nozzle.



2. The spike in the cap will pierce the tip of the vial.



3. Dispense drops with gentle pressure. Replace the cap after every use.

To be applied locally in the eye in the inferior conjunctival fornix.

- 1 drop up to 5 times during the 3 hours before surgery.
- 1 drop 3 to 5 times daily as a treatment for post-operative inflammation.

Photorefractive keratectomy: 2 drops within the hour prior to and following the surgery and then 4 drops within the 24 post-operative hours.

Do not inject, do not swallow.

If you take more DIFENASOL than you should

If you have exceeded the recommended dose, contact your physician or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Occasionally: a mild transient burning sensation and (or) visual disturbances could happen upon instillation.

Rarely: hypersensitivity reactions with itching and redness; photosensitivity (allergic reaction after sun exposure); punctate keratitis (lesions on cornea).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting

5. How to store DIFENASOL

Store this medicine under 30 °C, protected from light.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Do not use over one month after opening the bottle.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What DIFENASOL contains

- The active substance is sodium diclofenac
- The other ingredients are: boric acid, disodium edetate; benzalkonium chloride; polyoxyl 35 castor oil; tromethamine; water for injections.

What DIFENASOL looks like and contents of the pack

Colourless to pale yellow liquid, exempt of particles, contained in a 5 ml colourless LDPE (low density polyethylene) plastic bottle in a cardboard box.

Marketing Authorisation Holder

Exphar s.a.

Zoning Industriel Sud, Zone II

Avenue Thomas Edison 105

1402 Thines

Belgium

Phone +32.067.68.84.00

Fax +32.067.68.84.19

Manufacturer

AHLCON PARENTERALS (INDIA) LIMITED

SP-918, Phase-III, Bhiwadi-301019,
District: Alwar (Rajasthan)
India

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