Dicloftil® *0.1% eye drops, solution*

FARMIGEA

Diclofenac sodium

COMPOSITION
1 ml contains, active substance: diclofenac sodium 1 mg
Excipients: arginine; boric acid; borax; povidone K25; macrogolglycerol ricinoleate; disodium edetate; water for injection.

PHARMACEUTICAL FORM AND CONTENTS
30 single-dose 0.5ml containers of 0.1% eye drops, solution

PHARMACOTHERAPEUTIC CATEGORY: ophthalmic anti-inflammatory

MARKETING AUTHORISATION HOLDER AND MANUFACTURER
FARMIGEA SpA, Via G.B. Oliva 8 - 56121 Pisa, Italy

THERAPEUTIC INDICATIONS
Inflammatory and possible painful states, of non-infectious origin, affecting the anterior segment of the eye especially in cataract surgery.

CONTRA-INDICATIONS
Individual hypersensitivity to any of the ingredients. As with other non steroidal anti-inflammatory drugs it is contraindicated in patients that experienced, after administration of acetylsalicylic acid or other prostaglandin-synthetasis inhibitor drugs, asthma attacks, urticaria or acute rhinitis.

PRECAUTIONS FOR USE
Do not wear soft contact lenses during treatment.
There are no specific efficacy and safety data in children, therefore Dicloftil is not recommended in children.

INTERACTIONS:
Not reported so far. Clinical data have shown that Dicloftil can be associated with steroid eye drops. In case of administration with other drugs, in order to improve absorption, there should be an interval of at least 5 minutes between the application of DICLOFTIL and the other treatment.

SPECIAL WARNINGS
No safety data is available about using Dicloftil during pregnancy and breast feeding. Due to this use of Dicloftil is not recommended, except in cases when the doctor has evaluated risks and benefits of the therapy.
In patients with increased risk of ulcers or corneal thinning for example during use of steroids in patients with concomitant diseases like rheumatoid arthritis, the use of diclofenac has been associated (in rare cases) to corneal ulcers or thinning. Most of these patients were treated for a very long time.
In the presence or at risk of inflammation with bacterial infection, a concomitant appropriate antibiotic therapy is necessary.
Patients with scotoma should not drive or use machines.
The solution should be used immediately after opening of the container that should be discarded even if the product is only partially used.

DOSAGE
According to medical prescription.

OVERDOSE
There is no risk of overdose due to accidental ingestion of Dicloftil.

UNDESIRABLE EFFECTS
The following undesirable effects were reported:
Occasionally: short lasting mild or moderate burning at the time of instillation.
Rarely: hypersensitivity effects like itching, redness, photosensitivity and punctate keratitis.
Please tell your doctor about any undesirable effect not described in this leaflet.
Rarely corneal ulcers or thinning were observed (see special warnings). In rare cases dispnea and asthmatic episodes were reported.
Following the instructions in this leaflet will reduce the risk of undesirable effects.
It is important to tell your doctor or pharmacist in case of any side effects not listed in this leaflet.

EXPIRY DATE AND STORAGE
Do not store above 25°C. The expiry date refers to unopened, correctly stored product. Do not use the product after this date.

Once opened the aluminium bag, the product may be stored at room temperature no loger than 28 days.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

This leaflet was last revised by AIFA in April 2009