Ketoftil *0.05% eye drops, solution*

FARMIGEA

Ketotifen

COMPOSITION
100ml eye drops, solution contain, active substance: Ketotifen fumarate 69mg, equal to 50mg of Ketotifen.
Excipients 10ml bottle: glycerol, benzalkonium chloride, water for injections

PHARMACEUTICAL FORM AND CONTENTS
10 ml bottle of 0.05% eye drops, solution

Marketing Authorization Holder:
FARMIGEA SpA, Via G.B. Oliva 8, 56121 Pisa, Italy

Manufacturer and final control:
FARMIGEA SpA, Via G.B. Oliva 8, 56121 Pisa, Italy

THERAPEUTIC INDICATIONS
Acute and chronic conjunctivitis and keratoconjunctivitis of allergic origin (spring, atopic and others).

CONTRA-INDICATIONS
Individual hypersensitivity to any of the ingredients or to chemically similar substances. Generally contraindicated in pregnancy (see Special warnings and precautions for use).

SPECIAL WARNINGS AND PRECAUTIONS FOR USE
The use of KETOFTIL in sensitive subjects may attenuate the reacting ability.
KETOFTIL may give rise during application to a slight burning sensation for a few seconds.
The presence of benzalkonium chloride makes KETOFTIL *eye drops* incompatible with soft contact lenses.
Pregnancy: even if animal studies did not show any negative effect of Ketotifen on the foetus, the use of Ketoftil in pregnancy should be limited to cases of real necessity, especially in the first three-month period.

INTERACTIONS WITH OTHER DRUGS
Although ketotifen may lead to interactions with tranquilizers, hypnotic drugs and alcohol, the low plasmatic concentrations resulting from ocular administration make unlikely the occurrence of these effects.

KEEP THE MEDICINE OUT OF THE REACH AND SIGHT OF CHILDREN

DOSAGE
1 drop into the conjunctival sac twice or more times daily according to medical prescription.

INSTRUCTIONS FOR USE

TO OPEN

TO CLOSE

Open the bottle by pressing the lid and unscrewing the cap at the same time. After use, close the container by screwing the cap tightly.

UNDESIRABLE EFFECTS

Slight burning, local irritation with reddening (hyperemia) and inflammation of the eyelid (blepharitis) have been reported only in rare cases. Please tell your doctor or pharmacist of any undesirable effect not reported in this leaflet.

EXPIRY DATE AND STORAGE

The expiry date printed on the box refers to the unopened correctly stored product. There are no special storage conditions.
Warning: do not use after the expiry date printed on the box.

The product should not be used after 30 days from first opening of the bottle.

This leaflet was last revised by the Ministry of Health in November 2003.