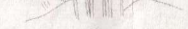
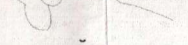
BRUNISTILL 0.025% eye-drops, solution
Ketotifen
Equivalent medicinal product

PHARMACO-THERAPEUTIC CATEGORY
Ophthalmologic products, other anti-allergic products.
THERAPEUTIC INDICATIONS
Symptomatic treatment of the seasonal allergic conjunctivitis.
CONTRAINDICATIONS
Hypersensitivity to the active ingredient (ketotifen) or to whatever excipients.
USE PRECAUTIONS
None
INTERACTIONS
If you are using other ocular products, please wait at least 5 minutes from one application and the other.
Inform the physician or the chemist if recently you assumed whatever other medicinal product even among those without prescription.
SPECIAL WARNINGS
Pregnancy and lactation
We have no clinical data on the use of BRUNISTILL during pregnancy. Caution is recommended prescribing the medicinal product to pregnant women.
Even if studies on animals after oral administration showed the excretion of the active ingredient in the mother milk, it is improbable that topical administration in woman could produce a quantity of active ingredient detectable in mother milk. Mothers who use BRUNISTILL eye-drops can breastfeed.
Ask for physician or chemist advice before assuming whatever medicinal product.
Effects on ability to drive and use machines
If the patient has blurring sight or sleepiness, avoid driving vehicles and machines use.

KEEP THE PRODUCT OUT OF THE REACH AND SIGHT OF CHILDREN

POSOLOGY
Adults, old people and children (over 3 years old): one drop of eye-drops in the conjunctival fornix twice a day. The content of a single-use container is enough for one administration in both eyes.
Container and content remain sterile till opening of their original closing. To avoid contamination risks do not touch any surface with the container tip.
TREATMENT LENGTH
According with the therapeutic needs and physician advice.
INDICATIONS FOR USE





To use the single dose bottle make the following steps:
1) tear a single dose bottle off the strip (see fig. A)
2) shake the little cap to empty it from the left liquid
3) open the single dose bottle by rotating the upper segment and pulling it. (see fig. B)
4) turn over the container and shake it carefully to let the liquid pour down.
5) pressing cautiously the little bottle drop the content in the eye according to physician's prescription.

OVERDOSAGE

Cases of overdose are not known.
The patient is recommended to ask the physician or the chemist to have explanations on the medicinal product use.
The oral assumption of one single-dose pipette would be equal to 0.1 mg of ketotifen, equal to 5% of a daily oral dose recommended for a 3 years old child. The clinical results did not show severe signs or symptoms after ingestion of one dose up to 20 mg ketotifen.
In case of accidental ingestion/assumption of an exceeding dose of BRUNISTILL inform the physician or go to the nearest hospital.
For whatever doubt on the use of BRUNISTILL, ask the physician or the chemist.

UNDESIRABLE EFFESCTS

As all medicinal products BRUNISTILL can cause undesirable effects even if not to all persons.
At the recommended dose the following undesirable effects are reported:
Eye pathologies:

- Common effects: ocular irritation, ocular pain, keratitis punctata.
- Uncommon effects: blurred sight (during instillation), dry eye, palpebral troubles, conjunctivitis, photophobia, conjunctival haemorrhage.

Pathologies of nervous system:
Uncommon effects: headache
Systemic pathologies and conditions relevant to the administration point:
Uncommon effects: sleepiness
Cutis and sub-cutis tissue pathologies:
Uncommon effects: rash, eczema, urticaria
Gastro-intestinal pathologies:
Uncommon effects: mouth dryness
Immunitary system troubles:
Uncommon effects: hypersensitivity
The respect of the instructions contained in this insert reduces the risk of undesirable effects.
Inform the physician if one of the undesirable effects worsen, or if an undesirable effect not listed in this insert appears.

EXPIRY AND STORAGE

Store at a temperature not higher than 25°C.
Please pay attention to the expiry date printed on the box. This data is valid for the product in its unopened packaging correctly stored.
Attention: Do not use the product after expiry date printed on the box.

The medicinal products must not be thrown in the drainage water and in the home waste. Ask the chemist how to waste the medicinal products you do not use any more. This will help to protect the environment.

COMPOSITION

A single-dose container of 0.5 ml contains:
Active ingredient:
Ketotifene 125 micro-grams (as hydrogen fumarate), equal to 250 micro-grams/ml
Excipients: Glycerol, sodium hydroxide, purified water.

PHARMACEUTICAL FORM AND CONTENT

0.025% eye-drops, clear, colourless solution. 20 single-dose containers.

M.A. HOLDER

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MANUFACTURER

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