COMBISTILL 0,3% + 0,1% eyedrops, suspension
Tobramycin and Desamethasone
Equivalent Medicinal Product

PHARMACO-THERAPEUTIC CATEGORY
Corticosteroids and antimicrobial associations.
THERAPEUTIC INDICATIONS
COMBISTILL is indicated to treat the ocular inflammations when it is necessary a corticosteroid and when it is present an ocular infection or the risk of ocular infections in adults and children of two years and older.
CONTRA-INDICATIONS
COMBISTILL is contra-indicated in the following cases:
a) Endo-ocular hypertension;
b) Acute Herpes simplex and the greatest part of the other diseases due to cornea virus in acute ulcerative phase, except association with specific chemiotherapy for the herpetic virus, conjunctivitis with ulcerative keratitis also in its initial phase (fluorescein test +). In the viral herpetic keratitis it is not advised the use that can be eventually allowed under the strict control of the oculist;
c) eye tubercolosis;
d) eye mycosis;
e) acute purulent ophthalmias, purulent conjunctivitis and purulent and herpetic blepharitis that can be masked or become severe because of corticosteroid products;
f) stye;
g) hypersensitivity to the active subatnces or to one of the excipients.
USE PRECAUTIONS
In case of treatments prolonged for over than 10 days, it is suitable to go on with frequent controls of the eye tone. This is particularly important in paediatric patients treated with products containing dexamethasone, as the risk of ocular hypertension induced by steroids can be greater in children younger than six years and it can be shown before than the steroids answer in adults. The treatment frequency and length must be carefully evaluated and the intra-ocular pressure (IOP) must be monitored since the treatment beginning, considering that the risk of an increase of the IOP induced by steroid is higher and it is shown early in paediatric patients.
It is also known that the prolonged use of corticosteroids could cause glaucoma, damage to ocular nerves, acuity and visual field defects, posterior sub-capsular cataract, or it can favour the secondary ocular infections starting. It is advisable an uninterrupted application for over than a month.
The prolonged use of antibiotics can favour the development of resistant micro-organisms: if this should happen of if no clinical improvement is noted within a certain period of time, stop the use of the product and start a suitable therapy.
To be used under the direct control of the physician.
INTEREACTIONS
Inform the physician or the pharmacist if whatever other medicinal product was assumed recently also those without the physician prescription.
The component tyloxapol is not compatible with tetracycline.
SPECIAL WARNINGS
Pregnancy and lactation
Ask for advice to the physician or the pharmacist before taking whatever medicinal product.
In pregnant women the product has to be administered in case of real need, under the direct control of the physician.
It is not known if the product is excreted with the mother milk, for this reason the product must be administered cautiously and under the direct physician control in women who are breast-feeding.
Effects on the driving ability and the use of machineries
COMBISTILL does not interfere on sight.
Like all the medicinal products for ophthalmic use, if at the moment of application should occur a temporary blurred vision, it is necessary to wait that the vision returns normal before driving or use machineries.
Important information on some excipients of COMBISTILL
COMBISTILL contains benzalkonium chloride which can cause eye irritation.
Avoid the contact with soft contact lenses.
Take out the contact lenses before the application and wait at least 15 minutes before wearing them again.
It is known the decolorating action on the soft contact lenses.
DOSE, WAY AND TIME OF ADMINISTRATION
Instill 1 or 2 drops 4-5 times a day according to the physician advise.
Paediatric patients
COMBISTILL eye-drops can be used in children over two years old at the same doses used for adults. The safety and efficacy in children younger than two years are not fixed and there are no available data.
Use instructions
COMBISTILL is for ocular use only.
Do not touch the eye or the area around the eye with the dropper tip. This can be polluted with bacteria that can cause ocular infections potentially responsible of severe damages to eyes, till the sight loss. Avoid the possible pollution of the container, avoid the contact of the dropper tip with whatever surface.

Wash always the hands before instilling the eye-drops
Shake before use
1. To open the bottle unscrew the cap.
2. Tilt your head back and low down slightly the lower eyelid to form a pocket between the eyelid and the eye
3. Push lightly the bottle turned updown to drop one or two drops into the eye according to the physician prescription. Do not touch the eye, the eyelid or whatever other thing with the dropper tip. Keep the eye close, push the corner of the closed eye (next to the nose) for one minute.
4. Repeat 2 and 3 with the other eye if the physician has prescribed to do this.
Close the bottle immediately after use screwing in the cap till it is well closed. Do not screw in excessively.
The dropper tip drops a drop of fixed volume; for this reason the dropper hole does not be enlarged. After having instilled all the doses, it is possible that some COMBISTILL remains into the bottle. Do not try to take out of the bottle the exceeding COMBISTILL.

OVERDOSAGE

Considering the topical, ocular administration route it is hard that cases of over-dosage occur. All the same if this should occur, wash accurately the eye with water.
In case of accidental assumption of an excessive dose of COMBISTILL inform immediately the physician or contact the nearest hospital.

For whatever doubt on the use of COMBISTILL, ask the physician or the pharmacist for information.

UNDESIRED EFFECTS

Like all the medicinal products, COMBISTILL can cause undesired effects though not all persons have them.
The undesired effects pointed out after the use of the association steroid/antibiotic can be of one component only or to both of them also if it is not known in what percentage. The side effects due to steroid component are: increase of endo-ocular pressure with the possibility that glaucoma occurs after 15-20 days of topical application in predisposed patients; posterior sub-capsular cataract formation after prolonged treatments; development or worsening of bacterial infection by Herpes simplex or fungi; cicatrization delay; manifestation, after prolonged administrations of serious side effects such as the sclera thickening, mydriasis, eyelids relaxation.
The most frequent secondary effect after tobramycin topical use is hypersensitivity with swelling, eyelid itching and conjunctival erythema. These reactions are shown in less than 3% of patients and are common to the other aminoglycoside antibiotics. When tobramycin is administered at the same time by topical and systemic route, it is necessary to control the total serum concentration.
In case undesired effects appear, especially if different from the described ones, the patient is invited to communicate them to the physician.

EXPIRY AND STORAGE

KEEP COMBISTILL OUT OF THE REACH AND SIGHT OF CHILDREN
Expiry: see the expiry date indicated on the box.
Attention: do not use after the expiry date printed on the external box and on the label.
The expiry date is referred to the product in its entire packaging, correctly stored.
Do not store at temperature higher than 25°C. Do not refrigerate or freeze it. Store in its original packaging to protect the medicinal product from light.
VALIDITY AFTER FIRST OPENING
The product must be used within 28 days after first opening
The medicinal products must not be disposed in the water drain and in the household waste. Ask the pharmacist how to dispose the medicinal products you do not use any more. This will help to protect the environment.

COMPOSITION

A bottle of 5 ml contains:
Active ingredients: tobramycin 3 mg, desamethasone 1 mg
Excipients: benzalkonium chloride, disodium edetate, sodium chloride, sodium sulphate, sodium hydroxide (pH regulator) or sulphuric acid (pH regulator), tyloxapol, hydroxyethylcellulose, water for injection.

PHARMACEUTICAL FORM AND CONTENT

Eye-drops, suspention, 1 bottle of 5 ml with dropper

Italian M.A. holder and Manufacturer:

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