NetilDex 0,1%+0,3%

Eye drops, solution

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Dexamethasone + Netilmicin

Composition:
Multidose eye drops
1 ml contains:
Active principles: Dexamethasone disodium phosphate 1.32 mg (equivalent to Dexamethasone 1 mg) and Netilmicin sulphate 4.55 mg (equivalent to Netilmicin 3 mg).

Excipients: Sodium citrate – Monosodium phosphate monohydrate – Disodium phosphate dodecahydrate – Benzalkonium chloride - Purified water

Single-dose eye drops
1 ml contains:
Active principles: Dexamethasone disodium phosphate 1.32 mg (equivalent to Dexamethasone 1 mg) and Netilmicin sulphate 4.55 mg (equivalent to Netilmicin 3 mg).

Excipients: Sodium citrate – Monosodium phosphate monohydrate – Disodium phosphate dodecahydrate – Purified water

Pharmaceutical form and content:
5 ml bottle eye drops, solution
15 and 20 single-dose containers with 0.3 ml eye drops, solution each

Pharmacotherapeutic classification:
Corticosteroids and Antiinfectives in combination

Marketing Authorisation Holder:
S.I.F.I. S.p.A. –via Ercole Patti, 36 - 95020 Lavinaio - Aci S. Antonio (Catania) - ITALY

Manufacturer:
S.I.F.I. S.p.A. – Manufacturing site in Aci S. Antonio (CT) - ITALY

Therapeutic indications:
Inflammatory ocular conditions of the anterior segment of the eye, either post-operative or not, in the presence or at risk of bacterial ocular infection.

Contraindications
NETILDEX is contra-indicated in the following cases:
Patient's hypersensitivity to active substances (netilmicin or dexamethason), aminoglycosidic antibiotics, or to any of the excipients.
Moreover, since the product contains corticosteroids, NETILDEX is contraindicated to patients affected by:
- intraocular hypertension (glaucoma);
- herpetic keratitis or other ocular infections caused by herpes simplex;
- viral diseases of the cornea and of the conjunctiva;
- ocular fungal diseases;
- mycobacterial ocular infections (i.e. tuberculosis of the eye).

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Precautions for use:
Prolonged use of corticosteroids in susceptible patients may result in an increase of intraocular pressure with possible damage to the optic nerve (glaucoma) and defects in visual acuity. Intraocular pressure should be routinely monitored in case of lasting treatments (longer than 15 days).

Prolonged use of corticosteroids may also cause: 1) posterior subcapsular cataract formation 2) delayed wound healing, 3) decrease of the host response and thus increased hazard of secondary ocular infections, in particular of fungal or viral nature. In purulent infections of the eye, corticosteroids administration may mask infection. Several ocular diseases and a prolonged use of corticosteroids may determine corneal and scleral thinning. In such cases scleral or corneal perforations have been known to occur with the use of topical steroids.

Should no significant clinical improvement be reported within a relatively short period of time or should any irritation or sensitisation phenomena occur, it is necessary to discontinue treatment and start an adequate therapy.

Studies on Netildex in children are not available, therefore, in paediatric patients the product should be administered only in case of real need and under direct medical control.

NETILDEX multidose eye drops contains benzalkonium chloride as a preservative, which may cause ocular irritation and discolour contact lenses. Therefore, during the use of Netildex multidose eye drops, wearing soft contact lenses should be avoided. Should the contemporary use of NETILDEX and soft contact lenses be necessary, it is advised the use of NETILDEX single-dose, preservative-free eye drops. In this case, remove the contact lenses and wait at least 20 minutes after the instillation of Netildex single dose eye drops before inserting the lenses again.

To be used under direct medical control.

Interactions:
In clinical studies no interactions have been reported using NETILDEX in association with other drugs.

Special warnings:
Use during pregnancy and lactation
In pregnant women the medicinal product shall be used in case of real need and under direct medical control. It is not known whether NETILDEX is excreted in maternal milk, therefore the product should not be administered in breast-feeding women.

Use in children
Safety and efficacy of NETILDEX in children has not been demonstrated. **Therefore, in paediatric patients the product should be administered only in case of real need and under direct medical control.**

Effects of NETILDEX on the ability to drive and use machines are unknown.

Posology and method of administration:
Instil 1 drop in the conjunctival sac 4 times daily, or according to medical prescription.

Multidose eye drops
While administering the product avoid touching the eye or any surface, including hands, with the tip of the container. Close the bottle immediately after use.

Single-dose eye drops
NETILDEX single-dose eye drops is to be used immediately after opening. Any unused solution must be discarded. Make sure single-dose container is intact before use.

Undesirable effects
Both active substances may contribute to possible undesirable effects, although it is not known in which measure.

Possible undesirable effects of corticosteroids are: 1) an increase of the intraocular pressure after 15-20 days of topical administration in susceptible subjects and patients with glaucoma, 2) posterior subcapsular cataract formation following prolonged treatments, 3) occurrence or worsening of herpes simplex or fungal infections, 4) delayed healing. In all the above cases, it is recommended to discontinue treatment and start an adequate therapy.

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Hypersensitivity, which is the most common undesirable effect of Netilmicin, topically used, may appear as conjunctival hyperemia, burning and itching. Such phenomena may be found in less than 3% of the treated patients and are possible also after topical use of other aminoglycosidic antibiotics.

If you notice any side effects not mentioned in this leaflet, please inform your doctor.

Expiry and storage
Expiry date is indicated on the outer package

Warning: do not use the medicinal product after the expiry date indicated on the package.

Store in the original container and keep the container in the outer box

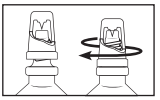
Multidose eye drops: do not use the product and discard the bottle 28 days after first opening.
Store below 30 °C
Store in the original container and keep the container in the outer box

Single-dose eye drops
Store below 30 °C
The product does not contain preservative: after administration the single-dose container and the unused content should be discarded.

KEEP THE PRODUCT OUT OF REACH AND SIGHT OF CHILDREN

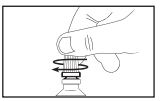
Directions for use

Multidose eye drops



Close the bottle by screwing the spike top thoroughly. Screw thoroughly the spike top to pierce the bottle. (picture 1)

Unscrew the spike top, reverse the bottle and instil by exerting a slight pressure on it. (picture 2)



Close the bottle by screwing the spike top thoroughly. (picture 3)

Single-dose eye drops

Make sure that the single-dose container is intact.
Pull apart the single-dose container from the strip (picture 4).

Open by turning the upper part without pulling (picture5).

Reverse the bottle and instil 1 drop by exerting a slight pressure on it (picture 6).

The product does not contain preservative: after administration the single-dose container and the unused content should be discarded.

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