

Package Insert: Patient information leaflet

Netildex 3 mg/ml / 1 mg/ml Ophthalmic Gel Netilmicin/Dexamethasone

Read this leaflet carefully before using this medicine, because it contains important information for you.

- Keep this leaflet, you may need to read it again.
- Contact your doctor or pharmacist if you have any queries.
- This medication has been prescribed for you only. Do not pass it on to others, as it could be dangerous, even if their symptoms are the same as yours.
- If you experience any of these side effects or others not listed in this leaflet, contact your doctor or pharmacist. See section 4.

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1. What is Netildex and what is it used for?

The active substances in Netildex are netilmicin and dexamethasone.

Netilmicin is an antibiotic that works by killing the bacteria that cause infections.

Dexamethasone is a corticosteroid that helps relieve inflammation and redness.

Netildex is used in adults to reduce inflammation and to kill bacteria in the eyes when they are infected or likely to be infected with bacteria, including after surgery.

Consult your doctor if your symptoms do not improve or worsen after your prescribed treatment period.

2. What you should know before using Netildex

Do not use Netildex:

- if you are allergic to netilmicin, dexamethasone, aminoglycoside antibiotics or any other ingredients of this medicine (listed in section 6);
- if your doctor told you that your eye pressure is too high;
- if you think you have a viral or fungal infection in or around your eye;
- if you have, or have previously had, a viral eye infection caused by the Herpes simplex virus (HSV);
- if you have conjunctivitis with ulcerative keratitis, even in the early stages (a positive fluorescein test);
- if your doctor told you that you have an eye infection caused by a bacteria known as mycobacteria;
- on children under three years of age;
- if you have an eye infection due to tuberculosis;
- if you are breast-feeding.

Warnings and precautions

Consult your doctor or pharmacist before using Netildex.

Consult your doctor if you notice swelling and weight gain around your torso and face, as these are usually the first signs of a syndrome called "Cushing syndrome". Suppression of adrenal gland function may develop after stopping prolonged or intensive treatment with Netildex. Consult your doctor before stopping treatment on your own. These are especially significant risks for children and patients being treated with a medicine called ritonavir or cobicistat.

This product should be used with caution in patients with impaired corneas and in cases where the patient is using other ophthalmic products containing phosphates (see section 4).

Patients without pre-existing corneal impairment do not appear to be at risk.

Contact your doctor if you experience blurred vision or other vision complaints.

Children and adolescents

Netildex is contraindicated in children under 3 years of age.

No data is available for children over 3 years of age and adolescents.

For external use only

Only use Netildex on the surface of the eye. This medicine should not be injected or swallowed.

If you use Netildex for a prolonged period:

- your eye pressure could increase, damaging the optic nerve and causing impaired vision. If you are using Netildex for a prolonged period, your eye pressure should be checked regularly by your doctor;
- you may develop cataracts;
- healing processes may be slowed;
- as a result of a lowered immune system, your body may not effectively fight off other types of eye infection, particularly viral or fungal infections;
- pus-producing eye infections may get worse with the use of corticosteroids or may make it harder to identify the type of bacteria causing the infection;
- in diseases that cause thinning of the eye surface, the use of corticosteroids may cause corneal perforations or perforations of the “white part of the eye” (sclera);
- you may develop an allergy to the antibiotic in the product.

Before using Netildex, tell your doctor if:

- you have glaucoma or a family history of glaucoma;
- you have corneal issues;
- you are taking other medications containing phosphates. Your doctor will check your cornea on a regular basis.

Other medicines and Netildex

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines or other ophthalmic medicines, including non-prescription medicines.

Consult your doctor or pharmacist before taking Netildex if you are taking any of the following medicines:

- any other antibiotics, in particular polymyxin B, colistin, viomycin, streptomycin, vancomycin and cephaloridine. Using other antibiotics at the same time as Netildex may increase the risk of kidney problems, hearing problems, or affect how the antibiotics given in combination with Netildex work;
- cisplatin, a chemotherapy drug;
- diuretics (medicines that reduce water retention), such as ethacrynic acid and furosemide;
- anticholinergic drugs (drugs that block glandular secretion), such as atropine;
- ritonavir or cobicistat, as they can increase the level of dexamethasone in your blood.

Other medicines for ophthalmic use and Netildex

If you are using other ophthalmic products, allow at least 5 minutes between applications. Ointments should be used last.

Pregnancy and breastfeeding

If you are pregnant, think you may be pregnant or plan to become pregnant, or if you are breastfeeding, ask your doctor or pharmacist for advice before using this medicine.

Pregnancy

It is recommended that you do not use Netildex during pregnancy unless your doctor deems it necessary.

Breastfeeding

You should not use Netildex if you are breastfeeding.

Driving and operating machinery

If you are using Netildex, you may experience temporary blurred vision. If this occurs, do not drive or operate machinery until your vision is clear again.

Netildex ophthalmic gel contains monosodium phosphate monohydrate and disodium phosphate dodecahydrate

This medicinal product contains 0.12 mg of phosphate buffer per drop, equal to 2.34 mg/ml.

In cases of severe damage to the outermost transparent layer of the eye (the cornea), in very rare cases, phosphates may cause opaque spots on the cornea due to calcium deposits building up during treatment (see section 4).

3. How to use Netildex

Always use this medicine exactly as prescribed by your doctor. Consult your doctor or pharmacist if you have any queries.

Posology

Adults

The recommended dose is **1 drop 2 times a day**, or as prescribed by your doctor.

Children

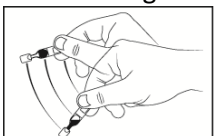
Netildex is contraindicated in children under 3 years of age.

Instructions for use

- 1) Wash/sanitise your hands thoroughly.
- 2) Separate the single-dose vial from the strip.



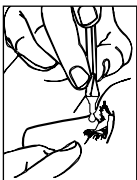
- 3) Make sure the single-dose vial is intact.
- 4) Hold the single-dose vial by the base and shake it downward.



- 5) Open the single-dose vial by twisting the top and pulling.



- 6) Apply the gel while making sure the tip of the single-dose vial does not touch the eye, the eyelid or any other surface; this avoids contamination.



If you handle the gel incorrectly, it can become contaminated with bacteria that can lead to eye infections. Using contaminated gel can result in serious damage to the eye and loss of vision.

If you use more Netildex than you should

No cases of overdose using Netildex have ever been reported.

If you use more gel than you should, you are unlikely to experience any problems and you should apply the next dose normally.

If the gel is accidentally swallowed or if excessive doses are used for a prolonged period, toxic effects may occur.

If you forget to use Netildex

Do not take a double dose to make up for forgetting a dose. If you forget to use the ophthalmic gel at the usual time, wait until the next dose is due and apply the dose normally.

If you stop taking Netildex

If you have any queries about using this medicine, contact your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine may cause side effects, although not everyone experiences them.

Possible side effects due to dexamethasone include:

- 1) increased pressure inside the eye;
- 2) cataract formation (posterior subcapsular);
- 3) developing or worsening of viral infections caused by the herpes simplex virus (HSV) or fungal infections;
- 4) delayed healing;
- 5) redness of the eyes (conjunctival hyperaemia);
- 6) Hormone problems: growth of extra body hair (particularly in women), muscle weakness and wasting, purple stretch marks on body skin, increased blood pressure, irregular or missing periods, changes in the level of protein and calcium in the body, stunted growth in children and adolescents, and swelling and weight gain of the body and face ("Cushing Syndrome") (see "Warnings and precautions" section).

Possible side effects due to netilmicin include:

The most common side effect with topical use of netilmicin is hypersensitivity. This manifests as reddening of the conjunctiva, burning and itching.

There is insufficient data available to determine the frequency of the individual effects listed.

In very rare cases (fewer than 1 in 10,000 people), some patients with severe damage to the clear layer in the front of the eye (cornea) have developed cloud-shaped spots on the cornea due to calcium deposits building up during treatment.

Side effects not known (frequency cannot be determined based on the data available): blurred vision.

Reporting side effects

If you experience any of these side effects or others not listed in this leaflet, contact your doctor or pharmacist. You can also report side effects directly through the Italian Medicines Agency (Agenzia Italiana del Farmaco) website at <https://www.aifa.gov.it/content/segnalazioni-reazioni-avverse>.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Netildex

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date displayed on the packaging after EXP.

The expiry date refers to the last day of that month and to the correctly stored intact product.

Store in the original packaging below 25°C.

Netildex does not contain preservatives and should be used immediately after opening; residual medicine should be discarded. After opening the aluminium sachet, the vials must be used within 28 days. After this period, any remaining vials must be discarded.

Do not dispose of any medicine via wastewater or in household waste. Ask your pharmacist how to properly dispose of medicines you no longer use. These measures help protect the environment.

6. Contents of the package and further information

What Netildex contains

- The active substances are netilmicin and dexamethasone. 1 ml of gel contains 3 mg of netilmicin (as netilmicin sulphate) and 1 mg of dexamethasone (as dexamethasone disodium phosphate).
- The other components are sodium citrate, monosodium phosphate monohydrate, disodium phosphate dodecahydrate, xanthan gum and purified water.

What Netildex looks like and contents of the package

Netildex is a consistent semi-solid ophthalmic gel that comes in 5 single-dose 0.4 ml gel vials wrapped in an aluminium sachet.

Packages of 10, 15 or 20 single-dose vials.

It may be that not all packages are marketed.

Marketing Authorisation Holder

SIFI S.p.A. - Via Ercole Patti, 36 - 95025 Aci S. Antonio (CT)

This leaflet was updated in July 2021.

Detailed and up-to-date information for this product is available by scanning the QR code, found on the leaflet and on the product packaging, with a smartphone.

The same information is also available at the following URL:

<http://qr.sifigroup.com/netildex-3-mgml-1-mgml-gel-oftalmico>