

Package leaflet: Information for the patient

NetilDex® 3 mg/ml + 1 mg/ml eye drops, solution in single-dose container Netilmicin / Dexamethasone

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Netildex is and what it is used for
2. What you need to know before you use Netildex
3. How to use Netildex
4. Possible side effects
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1. What Netildex is and what it is used for

Netildex contains two medicines: netilmicin and dexamethasone.

- Netilmicin is an antibiotic which kills bacteria.
- Dexamethasone is a steroid that reduces inflammation.

Netildex is used in adults to reduce inflammation and to kill bacteria in eyes that are swollen, irritated and likely to be infected by bacteria.

You must talk to a doctor if you do not feel better or if you feel worse at the end of the treatment.

2. What you need to know before you use Netildex

Netildex can be used in adults, including the elderly.
It is not recommended for anyone under 18 years of age.

Do not use Netildex:

- if you are allergic to netilmicin, dexamethasone, antibiotics that are known as aminoglycoside antibiotics (such as: tobramycin, kanamycin, amikacin, gentamicin, etc) or any of the other ingredients of this medicine (listed in section 6).
- if your doctor has advised you that the pressure in your eye is too high.
- if you think you may have a viral or fungal infection in or around your eye.
- if you have now, or have had in the past, a viral infection of the eye caused by the herpes simplex virus (HSV).
if your doctor has advised you that you have an infection of the eye caused by the bacterium known as mycobacteria.

Warnings and precautions

Talk to your doctor or pharmacist before using Netildex.

Talk to your doctor if you experience swelling and weight gain around the trunk and in the face as these are usually the first manifestations of a syndrome called Cushing's syndrome. Suppression of the adrenal gland function may develop after stopping a long-term or intensive treatment with Netildex. Talk to your doctor before stopping the treatment by yourself. These risks are especially important in children and patients treated with a drug called ritonavir or cobicistat.

Contact your doctor if you experience blurred vision or other visual disturbances.

If you use Netildex for a long time

- the pressure in your eye may increase and cause damage to the nerves in your eye and cause problems with your vision. If you use Netildex for more than 15 days the pressure in your eyes should be regularly checked by your doctor;
- you may develop cataract;
- wounds may take longer to heal;
- your body may not fight other types of infections in your eye as well as normal, such as fungal or viral infections;
- eye infections that produce a lot of pus, with the use of corticosteroids, may become worse or it may be more difficult to identify the type of bacteria causing the infection;
- the steroid in Netildex may cause thinning of the surfaces of the eye and even perforations;
- you may start to become allergic to the antibiotic in the eye drops.

Before you use Netildex tell your doctor if you

- have glaucoma or a family history of glaucoma;
- have problems with your cornea;
- are taking any other medicines containing phosphates. Your doctor will want to check your cornea at regular intervals;

Children and adolescents

Netildex is not recommended for use in children or adolescents (aged from birth to 18 years of age).

For external use only

Only use Netildex on the surface of your eye. This medicine should never be injected or swallowed.

Other medicines and Netildex

Netildex may interact with other medicines. Tell your doctor or pharmacist if you are taking or have recently taken any ophthalmic product or any other medicines, including medicines obtained without a prescription. You can still use Netildex with other ophthalmic products, but follow the instructions in section 3.

In particular, tell your doctor or pharmacist if you are taking:

- 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 it may affect how well the other antibiotics work;
- cisplatin, an anti-cancer drug;
- diuretics (medicines to reduce water retention) such as ethacrynic acid and furosemide;
- anticholinergic medicines (medicines that stop glands secreting), such as atropine;
- ritonavir or cobicistat, as this may increase the amount of dexamethasone in the blood;
- other medicines containing phosphates. Your doctor will monitor your cornea at regular intervals.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby ask your doctor or pharmacist for advice before taking this medicine.

Use in pregnancy

It is preferable not to use Netildex during pregnancy unless your doctor considers it is necessary.

Use in breast-feeding

Netildex should not be used if you are breast-feeding.

Driving and using machines

When you use Netildex your vision may become blurred for a short time. If this happens, do not drive or use any tools or machines until your vision becomes clear again.

Netildex contains phosphates

This medicine contains 0.18 mg phosphates in each drop which is equivalent to 3.66 mg/ml. If you suffer from severe damage to the clear layer at the front of the eye (the cornea), phosphates may cause in very rare cases cloudy patches on the cornea due to calcium build-up during treatment.

3. How to use Netildex

Always use this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The recommended dose is **one drop** in the affected eye **four times a day** or as prescribed. The usual treatment duration can vary from 5 to 14 days.

Do not change the dose of the eye drops without consulting your doctor.

Use in children and adolescents

Netildex is not recommended for use in children or adolescents (aged from birth to 18 years of age).

Contact lens wearers

Netildex in single-dose containers can be used while you wear contact lenses because it does not contain preservatives. However, it is strongly advised to avoid wearing contact lenses during an eye infection or inflammation. Contact lenses should not be worn during treatment with steroid eye drops due to increased risk of infection.

If you use Netildex with other eye drops

Wait at least 10 minutes between using Netildex and using the other eye drops or ointments. Eye ointments should be placed last.

Instructions for use

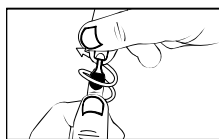
Make sure the single dose container is intact.

1. Wash your hands and sit or position your self comfortably.
2. Open the aluminium sachet containing the single-dose containers.
3. Separate the single-dose container from the strip (Picture 1) and put the unopened containers back into the sachet
4. Open by twisting the upper part without pulling (Picture 2) Do not touch the tip after opening the container.

5. Tilt the head back.
6. Use your finger to gently pull down the lower eyelid of your affected eye.
7. Invert the single-dose container and place the tip of the container close to, but not touching your eye. Do you not touch your eye or eyelid with the container tip (Picture 3).
8. Squeeze the single-dose container in order to administrate only one drop, then release the lower eyelid.
9. Close your eye and press a finger against the corner by the nose of the affected eye. Hold for 2 minutes.
10. Repeat in the other eye if your doctor has told you to do this.
11. Discard the single dose container after use.



(Picture 1)



(Picture 2)



(Picture 3)

If you use the eye drops incorrectly, it can become contaminated by bacteria which may lead to eye infections. Serious ocular damage and subsequent loss of vision may result from using contaminated eye drops.

If you use more Netildex than you should

If you use too many drops it is unlikely to have problems.
Apply the next dose as usual.

If you forget to use Netildex

Do not use a double dose to make up for a forgotten dose.
Apply the next dose as usual.

If you stop using Netildex

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The frequency of the individual effect listed cannot be estimated from the available data.

Eye disorders

Increased eye pressure, cataract formation after prolonged treatments, blurred vision, developing or worsening of a viral infection of the eye caused by the herpes simplex virus (HSV) or a fungal infection, delayed wound healing.

In very rare cases (less than 1 in every 10,000), some patients with severe damage to the clear layer at the front of the eye (the cornea) have developed cloudy patches on the cornea due to calcium build-up during treatment.

Immune system disorders

Local allergic reaction: redness of the conjunctiva, burning, pruritus.

Hormonal disorders

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 levels of protein and calcium in your body, stunted growth in children and teenagers and swelling and weight gain of the body and face (called 'Cushing's syndrome') (see section 2, "Warnings and precautions").

In all the above cases, it is recommended to discontinue treatment.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. 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 which is stated on the carton, sachet and container after EXP. The expiry date refers to the last day of that month.

Store below 30 °C.

Store the single-dose containers in the sachet in order to protect from light and moisture.

This medicine does not contain preservatives.

After first opening of a single-dose container, use immediately and throw away the single-dose container with any remaining contents after use.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Netildex contains

The active substances are dexamethasone 1 mg/ml (as dexamethasone disodium phosphate) and netilmicin 3 mg/ml (as netilmicin sulphate). Each single dose container contains 0.9 mg of netilmicin and 0.3 mg of dexamethasone.

The other ingredients are:

sodium citrate,
monobasic sodium phosphate monohydrate,
disodium phosphate dodecahydrate,
purified water.

What Netildex looks like and contents of the pack

Netildex is a clear, colourless or slightly yellow solution.

Netildex single dose eye drops:

Five single-dose containers, each containing 0.3 ml of Netildex eye drops, solution wrapped in an aluminium sachet.

Each pack contains 15 or 20 single-dose containers.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
SIFI Pharmaceuticals Limited
29/30 Fitzroy Square
London W1T 6LQ
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Manufacturer:
SIFI S.p.A.
Via Ercole Patti 36
95025 Aci S. Antonio (Catania) Italy

Distributed by:
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Building 1410
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Theale – Reading, RG7 4SA, United Kingdom

This leaflet was last revised in August 2022.

Detailed information on this medicine is
available on the website of
www.mhra.gov.uk.

**Detailed and updated information on
this product is available by scanning the
QR code included below or on the outer
packaging with a smartphone.**

**The same information is also available at
the following URL:**

<http://qr.sifigroup.com/1g155360/>

Scan:

