

## **PACKAGE LEAFLET: INFORMATION FOR THE PATIENT**

### **NETILDEX 3 mg/ml / 1 mg/ml eye drops, solution netilmicin and 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.

#### **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
5. How to store Netildex
6. Contents of the pack and other information

#### **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 therapy.

#### **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 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.

This product should be used cautiously in patients with compromised cornea and in case of concomitant use of other ophthalmic products containing phosphate (see Section 4).

Patients without pre-existing damage to their cornea do not seem to be at significant risk.

### **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.

Warning for people who practice sports: the product contains substances prohibited for doping. Any intake other than that indicated for therapeutic purposes, dosage, and route of administration is prohibited.

### **Use in 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.

### **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;
- wear contact lenses. You can still use Netildex, but follow the instructions for contact lens wearers in Section 3.

### **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 product, 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, if you suspect or planning to become pregnant, or are breast-feeding ask your doctor or pharmacist 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 breastfeeding.

### **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 multidose eye drops contains a preservative called benzalkonium chloride.**

This preservative may cause eye irritation or disruption to the surface of the eye. It can be absorbed by contact lenses and is known to discolour soft contact lenses. Therefore, avoid contact between this medicine and soft contact lenses.

### 3. How to use Netildex

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

#### Dosage

The usual dose is **one drop** in the affected eye **four times a day** or as prescribed.

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

If you wear contact lenses, you should remove them before using Netildex multidose eye drops. After using Netildex you should wait 15 minutes before putting your contact lenses back in.

#### If you use Netildex with other eye drops

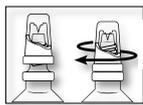
Wait at least 10 minutes between using Netildex and using the other eye drops.

#### Instructions for use

##### Multidose eye drops

Make sure the bottle is intact.

1. Wash your hands and sit comfortably.
2. Screw the cap down tightly in order to pierce the tip of the bottle. Unscrew the cap (Picture 1).
3. Tilt the head back.
4. Use your finger to gently pull down the lower eyelid of your affected eye.
5. Invert the bottle and place the tip of the bottle close to, but not touching your eye. Do not touch your eye or eyelid with the dropper tip.
6. Squeeze the bottle gently in order to administrate only one drop, then release the lower eyelid (Picture 2).
7. Close your eye and press a finger against the corner by the nose of the affected eye. Hold for 2 minutes.
8. Repeat in the other eye if your doctor has told you to do this.
9. Put the cap back on the bottle (Picture 3).



(Picture 1)



(Picture 2)



(Picture 3)

##### Single dose eye drops

Make sure the bottle is intact.

1. Wash your hands and sit comfortably.
2. Separate the single-dose container from the strip (Picture 4).
3. Open by rotating the upper part without pulling (Picture 5).
4. Tilt the head back.
5. Use your finger to gently pull down the lower eyelid of your affected eye.

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



(Figura 4)



(Figura 5)



(Figura 6)

Netildex single dose eye drops should be used immediately after opening. After administration, the single-dose container and unused contents should be discarded.

If you use incorrectly the eye drops, 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 ingest the entire content of a Netildex multidose container, you should consult your doctor immediately, as might occur side effects.

#### **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 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, 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.

#### Ormonal 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").

Not known side effects (frequency cannot be estimated from the available data): Blurred vision

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 national address reporting system

<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 which is stated on the carton and bottle label after Scad.

The expiry date refers to the last day of that month and to the unopened product, properly stored.

Store below 30 °C.

#### *Netildex multidose eye drops*

After first opening do not use this bottle for more than 28 days.

When you are not using Netildex multidose eye drops, keep bottle in the outer carton in order to protect from light.

#### *Netildex single dose eye drops*

The product does not contain preservatives.

Single-dose containers must be used immediately after they are opened; the residual medicine must be eliminated.

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).

The other ingredients are:

#### *Netildex multidose eye drops*

sodium citrate,  
sodium dihydrogen phosphate monohydrate,  
disodium phosphate dodecahydrate,  
benzalkonium chloride,  
purified water.

#### *Netildex single dose eye drops*

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

### **What Netildex looks like and contents of the pack**

Netildex is a clear, colourless slightly viscous solution.

#### *Netildex multidose eye drops*

One bottle containing 5 ml of Netildex eye drops, solution.

#### *Netildex single dose eye drops*

5 single-dose containers with 0.3 ml of Netildex eye drop wrapped in an aluminium sachet.

Carton box contains 15, 20 or 30 single-dose containers.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

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