

LEAFLET: INFORMATION FOR THE USER

Dexagenta-POS, eye drops 1 and 5 mg/ml

Dexamethasone sodium phosphate / Gentamicin sulfate

Read the entire 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.
- Do you have any questions? Please contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

Contents of this leaflet

1. What is Dexagenta-POS and what is it used for?
2. When should you not use this medicine or be extra careful?
3. How to use this medicine?
4. Possible side effects
5. How to store this medicine?
6. Contents of the packaging and other information

1. WHAT IS DEXAGENTA-POS AND WHAT IS IT USED FOR?

Dexagenta-POS is a preparation with a dual action, namely anti-infective (against infections), due to the antibiotic gentamicin with a broad action against various types of disease-causing bacteria. The highly effective corticosteroid dexamethasone is used to combat inflammatory symptoms. Gentamicin is not effective against viruses, fungi, and yeasts.

Dexagenta-POS combats inflammatory symptoms in the eye and prevents infections after surgeries, under strict medical supervision.

2. WHEN SHOULD YOU NOT USE THIS MEDICINE OR BE EXTRA CAREFUL WITH IT?

When should you not use this medicine?

You are allergic to any of the substances in this medicine. You can find these substances in section 6.

In acute purulent inflammations of the anterior part of the eye,

In lesions caused by fungi, viruses, infection with the cowpox virus, chickenpox,

Tuberculous conditions of the eye,

Increased pressure within the eye,

Eye conditions resulting from the sexually transmitted disease syphilis.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine.

Contact your doctor if you experience swelling and weight gain around the trunk and face as these are usually the first signs of Cushing's syndrome. Suppression of adrenal cortex function may occur after stopping a long-term or intensive treatment with Dexa-POS. Contact your doctor before stopping the treatment yourself. These risks are especially important in children and patients being treated with a medicine called ritonavir or cobicistat.

Contact your doctor if you experience blurred vision or other visual disturbances. When wearing soft contact lenses, during treatment with Dexagenta-POS, you cannot wear soft contact lenses. Unless your doctor has given other instructions.

Furthermore, prolonged local use of corticosteroids can cause increased eye pressure in some patients. It is advisable to have the eye pressure checked regularly.

Prolonged use can also lead to an increase in non-sensitive microorganisms, including fungi. If a new infection occurs during treatment, you should contact your treating doctor immediately.

The development of hypersensitivity to all antibiotics within the aminoglycoside group (including neomycin, framycetin, kanamycin, and tobramycin) to which gentamicin belongs, can occur. The chance of developing hypersensitivity increases with repeated use of medicines belonging to the aminoglycoside antibiotic group. You should discontinue treatment if a hypersensitivity reaction occurs.

Are you using any other medicines?

Are you using any other medicines besides Dexagenta-POS, or have you done so recently, or is there a possibility that you will use other medicines in the near future? Then tell your doctor or pharmacist. This also applies to medicines for which you do not need a prescription.

Simultaneous use of some other ophthalmic medicines can lead to an additional increase in intraocular pressure.

Inform your doctor if you are using ritonavir or cobicistat, as this may increase the amount of dexamethasone in the blood.

Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

There is insufficient data on the use of this product during pregnancy in humans to assess potential harm. In animal studies, corticosteroids have been shown to be teratogenic (= causing malformations in the fetus). The use of Dexagenta-POS eye drops during pregnancy should only occur under strict indication.

It is not known whether these medicines are excreted in breast milk. Given the low absorption of the active ingredients after ocular administration, Dexagenta-POS can be used during breastfeeding.

Driving and using machines

There is no known data on the effect of the eye drops on driving ability and the ability to use machines. From a theoretical point of view, an effect is unlikely.

Dexagenta-POS contains benzalkonium chloride and phosphates

This medicine contains 0.25 mg benzalkonium chloride in each 5 ml, corresponding to 0.05 mg/ml. Benzalkonium chloride can be absorbed by soft contact lenses and can change the

color of the contact lenses. You must remove your contact lenses before using this medicine and wait 15 minutes before reinserting them.

Benzalkonium chloride can also cause eye irritation, especially if you have dry eyes or a corneal condition (the transparent front layer of the eye). If you experience an abnormal sensation, stinging, or pain in the eye after using this medicine, contact your doctor.

This medicine contains 22.5 mg phosphates per 5 ml, corresponding to 4.5 mg/ml. If you have severe damage to the transparent front layer of the eye (the cornea), phosphates can in very rare cases cause cloudy spots on the cornea due to calcium accumulation during treatment.

3. HOW TO USE THIS MEDICINE?

Always use this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

The recommended dosage is to instill one drop in the affected eye 4 to 6 times a day.

The duration of treatment should not exceed 14 days. Monitoring the treatment outcome by your doctor is desired.

Unscrew the protective cap, turn the bottle upside down, tilt your head slightly back, and squeeze the bottle so that the required number of drops falls into the space between the eye and the lower eyelid. Close the bottle carefully after use. Avoid contact between the tip of the bottle and the eye or skin.

If you are using other ophthalmic medicines at the same time, wait about 15 minutes between the two applications. Eye ointments should be administered last.

If you notice that Dexagenta-POS is too strong or not strong enough, consult your doctor or pharmacist.

Use in children
No data available.

Have you used too much of this medicine?

If you have used too much of Dexagenta-POS, contact your doctor or pharmacist immediately.

Did you forget to use this medicine?

Do not take a double dose to make up for a forgotten dose.

If you stop using this medicine

Do not stop on your own initiative, always consult your doctor.

When using antibiotics, it is important to complete the treatment; if not all bacteria are killed, the symptoms may return.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following frequencies of occurrence have been established for the assessment of side effects:

Very common:	occur in more than 1 in 10 users
Common:	occur in less than 1 in 10 users
Uncommon:	occur in less than 1 in 100 users
Rare:	occur in less than 1 in 1000 users
Very rare:	occur in less than 1 in 10,000 users
Unknown	cannot be determined from the available data

Hormonal problems:

Unknown:

Growth of extra body hair (mainly in women), muscle weakness and muscle breakdown, purple stretch marks on the skin, increased blood pressure, irregular or absent menstruation, changes in the amounts of proteins and calcium in your body, growth disorders in children and teenagers, and swelling and weight gain of the body and face (called 'Cushing's syndrome') (see section 2, "When should you be extra careful with this medicine?").

Immune system disorders:

Rare:

Rare occurrence of hypersensitivity reactions and allergic contact hypersensitivity.

Eye disorders:

Sometimes:

Sometimes a burning sensation in the eye may occur immediately after instillation. This disappears on its own and does not necessarily mean the treatment should be stopped.

Rare:

With prolonged use, glaucoma (= green star due to increased intraocular pressure) or cataract (= clouding of the lens) may rarely occur in some patients.

Rare perforation of the cornea

Rare occurrence of a reinfection by microorganisms not sensitive to gentamicin

Unknown:

Blurred vision

Skin or subcutaneous disorders:

Rarely:

Rare occurrence of severe hypersensitivity reactions and allergic contact hypersensitivity (Stevens-Johnson syndrome).

In very rare cases, some patients with severe damage to the front transparent layer of the eye (the cornea) developed cloudy spots on the cornea due to calcium deposits during treatment.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:

Netherlands Pharmacovigilance Centre Lareb

Website: www.lareb.nl

By reporting side effects, you can help us obtain more information about the safety of this medicine.

HOW TO STORE THIS MEDICINE?

Store below 25°C. Do not store in the refrigerator or freezer. Keep in the original packaging.

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. This can be found on the label and on the carton after EXP. It includes a month and a year. The last day of that month is the expiry date.

Do not use for more than 1 month after opening the bottle.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer need. They will be destroyed responsibly and will not enter the environment.

CONTENTS OF THE PACK AND OTHER INFORMATION

What substances are in this medicine?

The active substances in this medicine are per ml 1 mg dexamethasone sodium phosphate and 5 mg gentamicin sulfate equivalent to 3 mg gentamicin.

The other substances in this medicine are benzalkonium chloride 0.05 mg/ml (preservative), potassium dihydrogen phosphate (E 450a), dipotassium hydrogen phosphate, sodium chloride, and water for injections.

What does Dexagenta-POS look like and how much is in a package?

Package with 1 dropper bottle with 5 ml solution for use in the eye.

Marketing authorization holder and manufacturer Registration holder:

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Dexagenta-POS is registered under RVG 16759.

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