

Package leaflet: Information for the user

Dexamethason GALEN 1 mg/ml oogdruppels, oplossing in verpakking voor eenmalig gebruik Dexamethasone phosphate

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 [Invented name] is and what it is used for
2. What you need to know before you use [Invented name]
3. How to use [Invented name]
4. Possible side effects
5. How to store [Invented name]
6. Contents of the pack and other information

1. What [Invented name] is and what it is used for

[Invented name] is an eye drop in single-dose container, which contains a substance called dexamethasone. This substance is a corticosteroid which inhibits inflammatory symptoms. [Invented name] is indicated for treatment of the inflammation of your eye(s). The eye should not be infected (red eye, secretions, tearing); otherwise a specific treatment of your infection should be combined (see section 2).

2. What you need to know before you use [Invented name]

DO NOT use [Invented name] if

- you are suffering from an **untreated eye infection** which could be bacterial (acute purulent infection), fungal, viral (herpetic virus, vaccine virus, varicella zona virus) or amoebic,
- you have **corneal damage** (perforation, ulcerations or lesions associated with incomplete healing)
- you have **raised eye pressure** known to be caused by glucosteroids (a type of corticosteroid)
- you are **allergic** (hypersensitive) **to dexamethasone sodium phosphate**, or any of the other ingredients of [Invented name].

Warnings and precautions

Talk to your doctor or pharmacist before using [Invented name].

DO NOT INJECT; DO NOT SWALLOW

Avoid contact between the dispenser tip and the eye or eyelids.

- Close monitoring of the eye is required throughout treatment and in particular:
 - for children and the elderly. More frequent monitoring is recommended

- if you have an eye infection. Only use [Invented name] if the infection is being treated
- if you are suffering from a corneal ulcer. Do not use a local dexamethasone treatment or [Invented name], unless inflammation is the main cause of delayed healing
- if you suffer from increased pressure in the eye. If you have already experienced adverse reactions to local steroid treatment, resulting in increased eye pressure, you are at risk of developing it again if treated with [Invented name]
- if you have glaucoma

Other warnings

- if you have severe allergic conjunctivitis that fails to respond to standard treatment, only use [Invented name] over a short period of time
- if you are diabetic, inform your ophthalmologist
- if you have a red eye that has not been diagnosed, do not use [Invented name]
- you should avoid wearing contact lenses during treatment with [Invented name].
- Contact your doctor if you experience blurred vision or other visual disturbances.

Cushing's syndrome

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

Children

Children should avoid continual, long-term treatment.

Other medicines and [Invented name]

Tell your doctor or pharmacist if you are using or have recently used or might use any other medicines.

- If you are using any other medicine to be applied in the eye, you should wait 15 minutes between each application.
- Tell your doctor if you are using ritonavir or cobicistat, as this may increase the amount of dexamethasone in the blood.
- Calcium phosphate deposits on the surface of the cornea have been observed when local steroids and beta-blockers are used at the same time as this medicine.

Pregnancy and breast-feeding

There is not sufficient information on the use of [Invented name] during pregnancy to evaluate the potential side effects. Therefore the use of [Invented name] during pregnancy is not recommended.

It is not known whether this medicine passes into breast-milk. However the total dose of dexamethasone is low, so [Invented name] can be used during 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.

Driving and using machines

As with all eye drops, temporary blurred vision, or other types of visual compromise may affect the ability to drive or use machines. Do not drive or use machines until normal vision has returned.

[Invented name] contains phosphates

This medicine contains 2.32 milligrams phosphates in each milliliter.

3. How to use [Invented name]

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

Dose

The recommended dose is 1 drop, 4 to 6 times daily in the affected eye.

In serious cases, treatment can start with 1 drop every hour and be reduced to 1 drop every 4 hours, once a favourable response has been observed. Gradual dose reduction is recommended in order to avoid recurrence of symptoms.

Elderly people: there is no need to adjust the dose.

Children: continual, long-term treatment should be avoided.

Method of administration

Ocular use: this medicine is intended to be administered into the eye.

1. **Wash your hands** thoroughly before using the product.
2. Open the pouch and detach one single-dose container from the strip. Put the remaining single-dose containers back in the pouch.
3. Twist off the cap. **Do not touch the tip** after opening the container.
4. Introduce **one drop into the affected eye**, while looking upwards and pulling the lower eyelid down with your finger.
5. Immediately after application, **apply light pressure** with your finger on the internal corner of the treated eye for few minutes (this reduces the risk of systemic reactions and increases penetration of the active substance into the eye).
6. **Discard** the single-dose container after use.

Duration of treatment

Treatment time usually varies from a few days to a maximum of 14 days.

If you use more [Invented name] than you should

Rinse the eye with sterile water and immediately contact your doctor or your pharmacist.

If you forget to use [Invented name]

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

If you stop using [Invented name]

Do not stop using the treatment abruptly. Always consult your doctor if you are considering stopping the treatment.

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

4. Possible side effects

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

Endocrine disorders:

Not known: frequency cannot be estimated from the available data

- 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 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").

Eye disorders:

Very common: may affect more than 1 in 10 people

- high intraocular pressure, after 2 weeks of treatment

Common: may affect up to 1 in 10 people

- discomfort, irritation, burning, stinging, itching and blurred vision after application. These are usually short-term and mild symptoms.

Uncommon: may affect up to 1 in 100 people

- allergic and hypersensitivity reactions to one of the ingredients in the eye drops,
- delayed healing
- cataract (opacification of the crystalline lens)
- infections
- glaucoma

Very rare: may affect up to 1 in 10,000 people

- inflammation of eye membranes (conjunctivitis)
- dilation of the pupil (mydriasis)
- facial swelling (facial oedema)
- drooping eyelids (ptosis)
- inflammation of the iris (uveitis)
- calcification of the cornea
- inflammation of the cornea (crystalline keratopathy)
- variations in the thickness of the cornea
- corneal swelling (oedema)
- ulcerations of the cornea
- perforation of the cornea

In very rare cases, if you suffer from severe damage to the clear layer at the front of the eye (the cornea), phosphates may cause cloudy patches on the cornea due to calcium build-up during 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 reporting system](#) listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Invented name]

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 single-dose container after EXP. The expiry date refers to the last day of that month.

After first opening the pouch, use the single-dose containers within 28 days.

After opening the single-dose container: use immediately and discard it after use.

Keep the single-dose containers in the pouch, in order to protect from light.

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 environment.

6. Contents of the pack and other information

What [Invented name] contains

- The active substance is dexamethasone sodium phosphate. Each millilitre of solution contains 1 mg of dexamethasone phosphate (as dexamethasone sodium phosphate).
- The other ingredients are disodium edetate, disodium phosphate dodecahydrate, sodium chloride and water for injections.

What [Invented name] looks like and contents of the pack

[Invented name] is a clear colourless to slightly brown eye drop solution supplied in single-dose containers.

Each single-dose container contains 0.4 ml of solution. The pack contains 10, 20, 30, 50 or 100 single-dose containers packed in pouches.

Houder van de vergunning voor het in de handel brengen en fabrikant

Vergunninghouder:

GALENpharma GmbH
Wittland 13
24109 Kiel
Duitsland

Fabrikant:

Genetic S.p.A.
Contrada Canfora
84084 Fisciano
Italië

In het register ingeschreven onder RVG 134359

This medicine is authorised in the Member States of the European Economic Area under the following names:

Deze bijsluiter is voor het laatst goedgekeurd in april 2026.