Package leaflet: Information for the patient

Dexeta 1.37 mg/ml eye drops, solution in single dose container

dexamethasone sodium 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 Dexeta is and what it is used for

Dexeta contains a substance called dexamethasone. It is a corticosteroid which inhibits inflammatory symptoms.
It is indicated for the treatment of non-infectious inflammation of your eye(s) such as the conjunctiva, the eyelid and/or the white part of the eye.

Tell your doctor if your condition does not improve after your prescribed length of treatment or if it worsens.

2. What you need to know before you use Dexeta

Do not use Dexeta:
- if you are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6).
- if you have high pressure inside the eye (ocular hypertension)
- if you have eye infection such as herpes simplex, viral infections of the cornea at ulcerous stage, tuberculosis or mycosis of the eye, acute purulent ophthalmia, purulent conjunctivitis, purulent herpetic blepharitis, hordeolum
- if you have conjunctivitis with inflammation and ulcers on the cornea (keratitis) even if it is at an early stage
- if you have corneal damages (corneal lesions and abrasions)

Warnings and precautions
Talk to your doctor or pharmacist before using Dexeta.

Close monitoring of the eyes is needed during the use of Dexeta and in particular:

- If the treatment is used for two weeks or longer, since you are at risk of developing increased ocular pressure.
- In case of long-term use (1 – 4 years) of ophthalmic corticosteroids, especially at high doses, since they can cause opacification of the crystalline lens (see section 4).

- If you have a viral infection, since the use of steroids may worsen/exacerbate the condition, which may lead to irreversible opacification of the cornea.
- If you have a disorder associated with thinning of the cornea.
- In case of inflammation of the cornea caused by herpes (herpes keratitis). The use of steroids may delay wound healing of damaged tissue and increase the incidence and spread of infections.
- In bacterial, viral or fungal conjunctivitis, since topical administration of the corticosteroid may mask evidence of progression of the infection.
- If you are using other phosphate-containing eye drops (see section 4).

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

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 Dexeta. 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.

In all the above cases and in case of hypersensitivity to any of the drug components, your doctor will discontinue the use of the eye drops and start an adequate treatment.

Contact lenses
Your doctor will ask you to remove your contact lenses prior to the administration of the drops. There is no information on the effect of this product on contact lenses. Therefore do not wear contact lenses until the effects of the drops have completely worn off.

Children and adolescents
The safety and efficacy of Dexeta in children have not been established.
In any case, continuous, long term use of corticosteroids should be avoided.

Other medicines and Dexeta
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines, including medicines obtained without a prescription.

You must talk to your doctor if you are taking other medicines containing phosphates. Your eye doctor will closely monitor your cornea at regular intervals.

The effect of the Dexeta can be decreased by:
- medicine used to treat epilepsy (barbiturates, phenytoin)
- medicine used to help you sleep or to relieve anxiety (sedative hypnotics)
- medicines used to treat various bacterial infections (rifampicin)
- medicines used to treat low blood pressure or relieve blocked nose (ephedrine)

Dexeta can decrease the effects of:
- medicines such as anticholinesterases (indicated for reduced intestinal movement and for myasthenia gravis (a muscle weakening disease))
- medicines used to treat infection of the eye caused by a virus
- medicines similar to aspirin called salicylates (indicated for inflammation, pain, fever and blood thinning)

Tell your doctor if you are taking ritonavir or cobicistat, as this may increase the amount of dexamethasone in the blood and its effects such as Cushing´s syndrome.

Tell your doctor if you are using atropine or related products, because used at the same time they might increase the pressure in the eye.
Dexeta can be used with other medicines for ophthalmic use, but it is important to follow the instructions in section 3.

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

Use during pregnancy
The use of this medicine during pregnancy is not recommended except when judged necessary by your doctor and under strict supervision.

Use of this medicine during breast-feeding
The use of Dexeta is not recommended during breast-feeding.

Driving and using machines
As with all eye drops, your vision may be blurred after putting the drops in. Wait until your vision is clear before driving or using machines.

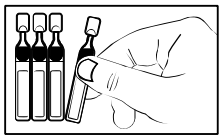
Dexeta contains phosphates
This medicine contains 0.13 mg phosphates in each drop which is equivalent to 3.66 mg/ml.
If you suffer from severe damage to the clear layer at the front of the eye (the cornea), phosphates may cause in very rare cases cloudy patches on the cornea due to calcium build-up during treatment.

3. How to use Dexeta

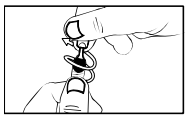
Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one drop in the affected eye(s) 3 to 4 times a day or as prescribed by your doctor.

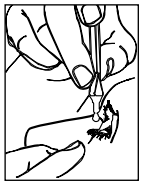
Instructions for use
1) Wash hands thoroughly before putting in the eye drops.
2) Make sure the single-dose container is intact.
3) Detach the single-dose container from the strip.



4) Open by turning the flap of the unit without pulling.



5) Sit or lie down and tilt head back and look up. Using your thumb and forefinger, gently and carefully pull the lower eyelid down.
6) Do not allow the tip of the single-dose container to touch the eye or eyelids, or any other surface, to avoid possible contamination.



Since sterility cannot be maintained after the individual single dose container is opened, any remaining contents must be discarded after administration.
Use in children and adolescents

Dexeta is not recommended for use in children.

If you use more Dexeta than you should
No cases of overdose have ever been reported with the use of Dexeta.
If you unintentionally instil more drops than you should, rinse thoroughly. Apply the next dose as usual.
If you unintentionally ingest the product, the doctor may consider a stomach cleansing.

If you forget to use Dexeta
Do not use a double dose to make up for a forgotten dose.

If you stop using Dexeta
Patients with pre-existing severe damage to their cornea, which is a sight-threatening condition should not stop treatment without consulting their treating doctor. Always tell your doctor if you are thinking about stopping the treatment.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

If you use Dexeta with other eye medicines
If you are using any other eye medicine, you should wait 5 minutes between using each medicine.
Eye ointments should be used last.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Most people who are treated with these eye drops do not suffer from any side effects.

Possible undesirable effects due to corticosteroids are the following:

Very common: may affect more than 1 in 10 people
- an increase of the intraocular pressure after 15-20 days of topical administration in predisposed subjects and patients with glaucoma.

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
- opacification of the crystalline lens (cataract formation) following long term use of corticosteroids;
- worsening/exacerbation of Herpes simplex or fungal infections;
- delayed wound healing.

Very rare: may affect up to 1 in 10,000 people
- perforation of the cornea;
- calcification of the cornea.

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 “Warnings and precautions”).

In all the above cases, patients should discontinue using the eye drops and start an adequate 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 HPRA Pharmacovigilance

Website: www.hpra.ie . By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dexeta

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 bottom of each unit, on the overwrap and on the carton after the letters "EXP". The expiry date refers to the last day of that month of the unopened and properly stored product.

This medicine does not require any special storage conditions.

The drops are for single use only and provided in single-dose containers. Once opened the single-dose container, use immediately and discard any unused product.
After aluminium sachet first opening, the single-dose containers remaining in the sachet have to be used within 28 days; after this period the unused single-dose containers must be discarded.

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 Dexeta contains

- The active substance is dexamethasone sodium phosphate. 1 ml of solution contains 1.37 mg dexamethasone phosphate equivalent to 1.5 mg of dexamethasone sodium phosphate.
- The other ingredients are sodium citrate, sodium phosphate monobasic monohydrate, disodium phosphate dodecahydrate, purified water.

What Dexeta looks like and contents of the pack

Dexeta 1.37 mg/ml eye drops, solution in single dose container is a colourless solution contained in 5 single-dose containers with 0.3 ml of eye drops which are wrapped in an aluminium sachet and packaged inside a carton box. Each individual single-dose unit contains 0.45 mg of dexamethasone sodium phosphate in 0.3 ml of solution.
The carton box contains 2 or 4 aluminium sachets.
Each carton box contains 10 or 20 single-dose containers.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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

This medicinal product is authorised in the Member States of the EEA under the following names:

Portugal	Etafry 1.5 mg/ml colírio, solução
France	Etartilen 1,5 mg/ml, collyre en solution
Spain	Etacortilen 1,5 mg/ml colirio en solución
Greece	Dexeta 1.5 mg/ml Οφθαλμικές σταγόνες, διάλυμα
Cyprus	Dexeta 1.5 mg/ml Οφθαλμικές σταγόνες, διάλυμα

Romania	Etacortilen 1.5 mg/ml picături oftalmice, solutie
Austria	Etacortilen 1,5 mg/ml Augentropfen, Lösung
Czech Republic	Etafry 1.5 mg/ml oční kapky, v jednodávkovém obalu
Germany	Etacortilen 1,5 mg/ml Augentropfen, Lösung
Ireland	Dexeta 1.37 mg/ml eye drops, solution in single dose container
The Netherlands	Etacortilen 1,5 mg/ml oogdruppels, oplossing
Poland	Dexeta 1.5 mg/ml krople do oczu, roztwór

This leaflet was last revised in