

Dexafree 1 mg/ml, eye drops, solution in single-dose container

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. WHAT DEXAFREE IS AND WHAT IT IS USED FOR

Dexafree contains dexamethasone, which is a corticosteroid used to stop inflammatory symptoms (such as pain, heat swelling and redness).

Dexafree is used to treat inflammation of your eyes.

If you have an infected eye (red eye, tears, mucous), you will be given another medicine to take at the same time as Dexafree. See Section 2.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE DEXAFREE

Do not use Dexafree

- if you are suffering from an eye infection that you are not using a medicine for,
- if you have damage on the surface of the eye (small holes, ulcers or injury which have not healed properly),
- if you have high pressure in the eye known to be caused by glucosteroids (family of corticosteroid medicines),
- if you are allergic (hypersensitive) to dexamethasone sodium phosphate, or any of the other ingredients of this medicine (listed in Section 6).

Warnings and precautions

Tell your doctor, pharmacist or nurse before using Dexafree.

DO NOT INJECT, DO NOT SWALLOW.

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

- close monitoring of the eye is required during the use of Dexafree and in particular:
 - for children and the elderly. More frequent monitoring is advised,
 - if you have an eye infection. Only use Dexafree if you are using an anti-infective medicine,

- if you have a corneal ulcer, an open sore on the surface of the eye with sometimes extreme pain, tears, squinting and loss of vision. Do not use Dexafree, unless inflammation is the main cause of delayed healing,
- if you suffer from high pressure in the eye. If you have already had high pressure in the eye after using an eye steroid medicine, you are at risk of having this again if you use Dexafree,
- if you have glaucoma, a condition which can cause damage to the optic nerve and may cause loss of sight.
- children: do not use for long-term treatment without a break.
- if you have severe allergic conjunctivitis (redness, swelling, itching and tears in the eye) that another medicine has not been able to treat, only use Dexafree for a short period of time.
- diabetic: if you are diabetic, tell your ophthalmologist or optician.
- if you have a red eye that has not been diagnosed, do not use Dexafree.
- contact lenses: do not wear contact lenses when you are using Dexafree.

Talk to your doctor if you notice swelling and weight gain around your middle and in your face as these are usually the first signs of a condition called Cushing's syndrome. Decrease in the function of the adrenal gland may develop after stopping a long-term or intensive treatment with Dexafree. 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.

Tell your doctor if you have blurred vision or other visual disturbances.

Other medicines and Dexafree

If you are using any other eye medicine, wait 15 minutes between using each medicine.

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

Using eye drops containing steroids and eye drops containing beta-blockers (to treat high pressure in the eye) together may cause settling of calcium phosphate on the surface of the eye.

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

Pregnancy and breast-feeding

There is not enough information on the use of Dexafree during pregnancy to know the possible side effects.

For this reason, the use of Dexafree during pregnancy is not recommended.

It is not known if this medicine is present in breast milk. However, the dose of Dexafree is low. Dexafree can be used when 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 using this medicine.

Driving and using machines

You may have blurred vision for a short time after using your drops. Wait until your vision is normal before you drive or use machines.

Dexafree contains phosphates

This medicine contains 80 micrograms phosphates in each drop.

3. HOW TO USE DEXAFREE

Dose

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

The usual dose is 1 drop, 4 to 6 times a day in the eye to be treated. If your condition is more serious, you may be told to start with 1 drop every hour and then change to 1 drop every 4 hours, after the medicine has started to work. It is important to lower the dose slowly to stop the condition getting worse again.

- In elderly people: there is no need to adjust the dose.
- In children: do not use for long-term treatment without a break.

Method of administration

Ocular use: this medicine is eye drops to be used in the eye.

- ① Wash your hands well before using these drops.
- ② Look upwards and pull the lower eyelid down with your finger. Put one drop into the eye to be treated.
- ③ Immediately after you have put the eye drop in, press lightly with your finger on the inside corner of your eye, nearest your nose for few minutes. This helps to stop the eye drops spreading into the rest of your body.
- ④ Throw away the single-dose container after use. Do not keep it to use it again.

Frequency of administration

4 to 6 times a day.

Duration of treatment

You will usually need to use your drops for a few days and no longer than 14 days.

If you use more Dexafree than you should

Rinse the eye with sterile water if you put too much medicine in your eye and your eye feels sore.

Immediately tell your doctor or pharmacist.

If you forget to use Dexafree

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

If you stop using Dexafree

Do not stop using this medicine suddenly. Always tell your doctor if you are thinking about stopping the treatment.

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

4. POSSIBLE SIDE EFFECTS

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

Endocrine conditions:

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 conditions:

Very common (may affect more than 1 in 10 people):

- high pressure in the eye after 2 weeks of using the drops.

Common (may affect up to 1 in 10 people):

- discomfort, irritation, burning, stinging, itching and blurred vision after use. These are usually mild and do not last long.

Uncommon (may affect up to 1 in 100 people):

- signs of an allergic reaction,
- healing which takes longer than expected,
- cloudy lens (cataract),
- infections,
- high pressure in the eye (glaucoma).

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

- inflamed surface of the of eye giving red eye, tears and irritation (conjunctivitis),
- wide pupil (mydriasis),
- swelling of the face (facial oedema),
- drooping eyelids (ptosis),
- inflammation of the eye which causes pain and redness (uveitis),
- settling of calcium on the surface of the eye (calcification of the cornea),
- inflamed surface of the eye giving blurred vision, dry eyes, sensitivity to light, burning, tears and a sandy sensation in your eye (crystalline keratopathy),
- changes in the thickness of the surface of the eye,
- swelling of the surface of the eye (corneal oedema),
- ulcer on the surface of the eye causing pain, tears, squinting and vision loss,
- small holes on the surface of the eye (perforation of the cornea).

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.

Reporting of side effects

If you get any side effects talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

You can also report side effects directly via the national reporting system:

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Ireland

HPRA Pharmacovigilance

Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE DEXAFREE

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.

Keep the single-dose containers in their sachet, to protect them from light.

After first opening the sachet: use the single-dose containers within 15 days.

After opening of the single-dose container: use immediately and throw away the single-dose container 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 environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Dexafree 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 Dexafree looks like and contents of the pack

Dexafree is a clear colourless to slightly brown eye drops solution supplied in single-dose containers.

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

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Laboratoires Théa
12, rue Louis Blériot
63017 Clermont-Ferrand Cedex 2
France

Manufacturer
EXCELVISION
Rue de la Lombardière
07100 ANNONAY
FRANCE

Or

Laboratoire UNITHER
1 rue de l'Arquerie
50200 Coutances
France

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

Bulgaria, Cyprus, France, Greece, Ireland, Poland, Portugal, Spain, Sweden and
United Kingdom..... DEXAFREE
Belgium, Luxembourg and the Net.....MONOFREE DEXAMETHASON
Austria and GermanyMONODEX
Italy and SloveniaDEXAMONO
Denmark, Finland and Norway MONOPEX

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