

**PACKAGE LEAFLET: INFORMATION FOR THE USER**  
**Dexafree® 1 mg/ml, Eye drops, solution in single-dose container**

(dexamethasone phosphate)

Your medicine is known as the above but will be referred to as Dexafree throughout the remainder of this leaflet.

**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 and 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 needed 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 betablockers (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 breastfeeding, 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 again.

**Frequency of use**

4 to 6 times a day.