

## **Package leaflet: Information for the user**

### **Dexamethasone phosphate 1 mg/ml eye drops, solution, preservative free** Dexamethasone phosphate (as 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 Dexamethasone eye drops is and what it is used for
2. What you need to know before you use Dexamethasone eye drops
3. How to use Dexamethasone eye drops
4. Possible side effects
5. How to store Dexamethasone eye drops
6. Contents of the pack and other information

The full name of your medicine is Dexamethasone phosphate 1 mg/ml eye drops, solution, preservative free which is presented in single-dose containers. In this leaflet the shorter name Dexamethasone eye drops is used.

#### **1. What Dexamethasone eye drops is and what it is used for**

Dexamethasone eye drops contains dexamethasone, which is a corticosteroid used to treat inflammatory symptoms (such as pain, swelling and redness).

Dexamethasone eye drops is used to treat inflammatory conditions affecting the front part of the eye that are not caused by infections.

#### **2. What you need to know before you use Dexamethasone eye drops**

##### **Do not use Dexamethasone eye drops:**

- if you are allergic to dexamethasone sodium phosphate or any of the other ingredients of this medicine (listed in section 6)
- if you are suffering from an eye infection that is untreated
- if you have damage to the surface of the eye (including, ulcers or injuries which have not healed properly), unless otherwise recommended by your ophthalmologist
- if you have high pressure in the eye known to be caused by steroids, unless otherwise recommended by your ophthalmologist.

#### **Warnings and precautions**

*DO NOT INJECT, DO NOT SWALLOW.*

*Avoid contact between the dispenser tip and the eye or eyelids. Keep out of sight and reach of children.*

Talk to your doctor or pharmacist before using Dexamethasone eye drops if the following apply to you, as close monitoring is needed:

- children and the elderly. More frequent monitoring is advised. If Dexamethasone eye drops is to be used by a child, do not use for a long time without a break.
  - if you have an eye infection, or have had viral eye infections in the past (eg, herpes). Only use Dexamethasone eye drops if you are using an anti-infective medicine, and are under the care of an ophthalmologist.
  - if you have a corneal ulcer, an open sore on the surface of the eye. Do not use Dexamethasone eye drops, unless you are under the care of an ophthalmologist
  - if you suffer from high pressure in the eye, or you have glaucoma (a condition which can cause damage to the optic nerve and may cause loss of sight). 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 Dexamethasone eye drops. 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 Dexamethasone eye drops for a short period of time.
- If you are diabetic, tell your ophthalmologist or optician that you are using Dexamethasone eye drops.
  - If you have a red eye that has not been diagnosed, do not use Dexamethasone eye drops.
  - If you usually wear contact lenses, avoid wearing contact lenses while you are using Dexamethasone eye drops.
  - 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 Dexamethasone eye drops. 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.

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

### **Children**

Use of Dexamethasone eye drops solution in children must be restricted. In children, continuous, long term use of corticosteroid eye drops should be avoided.

### **Other medicines and Dexamethasone eye drops**

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

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

Using eye drops containing steroids together with certain other eye drops (e.g. those containing beta-blockers to treat high pressure in the eye) may rarely cause calcium crystals to form on the surface of the eye.

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

### **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 or pharmacist for advice before taking this medicine.

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

For this reason, the use of Dexamethasone eye drops during pregnancy is not recommended.

It is not known if this medicine is present in breast milk. Dexamethasone eye drops should be used with caution whilst breast feeding.

### **Driving and using machines**

You may have blurred vision for a short time after using your drops. Do not drive or use machines until normal vision has returned.

### **3. How to use Dexamethasone eye drops**

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

This medicine should only be used in the eye (ocular use).

#### **Recommended dose:**

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 reduce the dose gradually in order to avoid the condition worsening again after you stop your medication.

#### Use in elderly people:

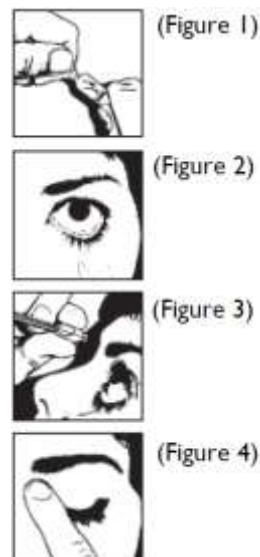
There is no need to adjust the recommended dose.

#### Use in children:

Do not use for long-term treatment without a break.

#### **Method of administration**

1. Open the foil sachet which contains 5 single dose containers. Write the date of first opening on the sachet. Discard any unused single dose container 28 days after opening the sachet.
2. Wash your hands well before using these drops.
3. Break off one single dose container from the strip and twist open the top of the single dose container (Figure 1).
4. Tilt your head back and pull your lower eyelid down slightly to form a pocket between your eyelid and eye (Figure 2). Put one drop into the eye to be treated. Do not allow the container to touch your eye or any area around your eye (Figure 3).
5. 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 2 minutes (Figure 4). This helps to stop the eye drops spreading into the rest of your body.
6. Throw away the single-dose container after use. Do not keep it to use again.



#### **Frequency of use**

As recommended by your doctor. Usually 4 to 6 times a day.

#### **Duration of treatment**

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

**If you use more Dexamethasone eye drops than you should**

Rinse the eye with sterile water if you have put too much medicine in your eye and your eye feels sore. Immediately tell your doctor or pharmacist.

**If you forget to use Dexamethasone eye drops**

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

**If you stop using Dexamethasone eye drops**

Do not stop using the treatment abruptly. 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.

**4. Possible side effects**

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

**Eye conditions:**

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

- increased pressure in the eye.

*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):*

- allergic reactions
- prolonged healing of wounds
- cataract (clouding of the lens inside the eye)
- infections
- glaucoma (caused by high pressure in the eye).

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

- conjunctivitis (inflammation of the surface of the eye, causing redness, watering and irritation)
- increase in the size of the pupil
- swelling of the face
- drooping eyelids
- inflammation inside the eye which causes pain and redness (uveitis)
- formation of calcium crystals on the surface of the eye
- swelling of the surface of the eye (the cornea)
- ulcers on the surface of the eye causing pain, watering, redness and vision loss perforation of the surface of the eye (the cornea).

*Not known (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").

**General conditions:**

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

- if used for prolonged periods the production of certain hormones may be reduced

In very rare cases, some patients with severe damage to the clear layer at the front of the eye (the cornea) have developed 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:

**UK:** Yellow Card Scheme

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

**Ireland:** HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2

Tel: +353 1 6764971, Fax: +353 1 6762517

Website: [www.hpra.ie](http://www.hpra.ie)

e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

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

## **5. How to store Dexamethasone eye drops**

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 overwrap of each unit and on the carton after EXP. The expiry date refers to the last day of that month. After opening the sachet, the unopened single-dose container can be stored for 28 days.

Do not store above 25°C. Store in original package in order to protect from light.

Do not refrigerate or freeze.

Opened single-dose containers should be discarded immediately after use, even if some solution remains.

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 Dexamethasone eye drops contains**

- The active substance is dexamethasone sodium phosphate. Each individual single-dose unit contains 0.4 mg of dexamethasone phosphate (as dexamethasone sodium phosphate) in 0.4 ml of solution.
- Dexamethasone phosphate 1 mg/ml eye drops, solution, preservative free also contains sodium chloride, disodium edetate, disodium phosphate dodecahydrate (E339) and purified water.

### **What Dexamethasone eye drops looks like and contents of the pack**

Each single-dose unit contains 0.4 ml Dexamethasone eye drops without preservative. There are five single-dose units per sachet. Each carton contains either four sachets (20 pack) or six sachets (30 pack). Not all pack sizes may be marketed.

### **Marketing Authorisation Holder:**

Alissa Healthcare Research Limited, Unit 5, Fulcrum 1, Solent Way, Whiteley, Fareham, Hampshire, United Kingdom, PO15 7FE

Alissa Healthcare Research Limited  
UK/H/5450/01/IB/006  
Variation to updated in line with PRAC

**Manufacturer:**

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

Ireland & United Kingdom: Dexamethasone phosphate 1 mg/ml eye drops, solution, preservative free

**This leaflet was last revised in 06/2017**