

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

### **Dropodex 0.1% w/v Eye Drops, solution**

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 Dropodex Eye Drops are and what they are used for
2. What you need to know before you use Dropodex
3. How to use Dropodex
4. Possible side effects
5. How to store Dropodex
6. Contents of the pack and other information

#### **1. What Dropodex Eye Drops are and what they are used for**

Each Dropodex single-dose container contains the active ingredient dexamethasone phosphate (as dexamethasone sodium phosphate), at a concentration of 0.1% w/v (1 mg/ml). Each Dropodex sterile single-dose container holds approximately 0.4 ml of solution. Dropodex belongs to the group of corticosteroids that suppresses inflammation.

Dropodex is used for:

- Certain cases of inflammation in the front of the eye such as the inflammation of the cornea, conjunctiva and iris and connective tissue.
- Hypersensitive reaction of the conjunctiva not responding to standard treatments.
- Treatment of inflammation of the eye, as long as the eye is not infected. Your doctor may sometimes use other drugs at the same time as Dropodex to make sure that your eye is treated effectively.

#### **2. What you need to know before you use Dropodex Eye Drops**

##### **Do not use Dropodex Eye Drops:**

- If you are allergic to dexamethasone sodium phosphate or any of the other ingredients of this medicine (listed in section 6).
- In case of bacterial eye infections (such as: acute purulent bacterial infections), fungal infections, viral diseases (for example: Herpes simplex, vaccinia, varicella zoster), or amoebiasis.
- In case of tuberculosis.
- In cases of damaged cornea (such as: perforation of the cornea), ulceration, lesions with incomplete formation of the covering tissue.
- In cases of increased intraocular pressure caused by glucocorticosteroids (these belong to the group of corticosteroids).

#### **Warnings and precautions**

##### **Talk to your doctor or eye specialist before using Dropodex Eye Drops:**

- If you have an eye infection.

- If you have increased pressure within the eye (glaucoma), or are at risk of developing glaucoma. Your doctor will check for this.
- 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 Dropodex 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 ritanovir or cobicistat.
- If you are using any other eye drops.

Wearing of contact lenses during treatment with corticosteroid eye drops must be avoided.

Long term, frequent use of corticosteroids can lead to the formation of cataracts (clouding of the lens in the eye).

### **Children and adolescents**

Use of Dropodex 0.1% w/v eye drops in children and adolescents must be restricted. In children, continuous, long term use of corticosteroid eye drops should be avoided.

### **Other medicines and Dropodex Eye Drops**

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

If you are already using eye drops to treat glaucoma it is possible that the dose may need to be adjusted if you are prescribed Dropodex.

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

If you are using more than one sort of eye drops leave five minutes between applications.

### **Pregnancy and 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 eye specialist for advice before taking this medicine. There is insufficient information available to determine the potential harmful effects on pregnancy. Dropodex should not be used during pregnancy and breast-feeding unless considered appropriate by your doctor or eye specialist.

### **Driving and using machines**

Your eyesight may become blurred for a short time following the use of Dropodex. You must not drive or operate hazardous machinery until your eyesight has returned to normal.

## **3. How to use Dropodex Eye Drops**

Always use this medicine exactly as described in this leaflet, or as your doctor has told you. Check with your doctor if you are not sure.

If your eye problem is severe, you may be asked to use these eye drops more frequently at first. The frequency can then be reduced as the eye gets better. More detailed instructions will be given to you by your doctor or pharmacist. Make sure you follow these instructions carefully.

### **Usual Dose**

The recommended dose is 1 drop in one or both eyes, 4 to 6 times a day in the affected eye. In severe cases, treatment may be started with 1 drop every hour at the start of the therapy but dosage should be reduced to 1 drop every 4 hours when a favourable response is observed. Do not stop using the treatment abruptly. Gradual tapering off is recommended in order to avoid a relapse. The duration of treatment will generally vary from a few days to a maximum of 14 days.

### Use in children and adolescents

Follow the instructions given by your doctor because the dose may vary.

**Do not** allow the tip of the single-dose container to touch your eye or areas around your eye. It may become contaminated with bacteria that can cause eye infections leading to serious damage to the eye, even loss of vision. To avoid possible contamination of the single-dose container, keep the tip of the container away from contact with any surface.

The solution from one individual single-dose container of Dropodex is to be used immediately after opening for administration to the affected eye(s). Since sterility cannot be maintained after the individual single-dose container is opened, a new single-dose container must be opened prior to each use and must be discarded immediately after administration.

### Instructions for use of Dropodex Eye Drops

1. Break off one single-dose container from the strip.
2. Open the single-dose container by bending/ twisting the tab (Figure 1)
3. Tilt your head backwards
4. Gently pull down the lower lid to form a pouch (Figure 2).
5. Place the dropper tip close to your eye, but do not touch the eye or lid, and gently squeeze the single-dose container to release one drop into your eye. (Figure 3).
6. Close the eye for about 30 seconds and at the same time gently press a finger against the corner of the closed eye, nearest the nose. (Figure 4).
7. Some drops may roll down your face. This is normal. The eye holds less than one drop. Wipe away the excess with a clean tissue. If the drop of medication is not retained for any reason, another drop should be dropped into the eye pouch.
8. If you use more than one type of eye medicine, wait five minutes before putting in the next one. This prevents the first drop from being washed away. Eye ointments should be applied last.
9. Repeat instructions 3-8 for the other eye.
10. After instillation, discard the used single-dose container even if there is solution remaining.
11. Store the remaining single-dose containers in the foil sachet. After opening the sachet, the unopened ampoules can be stored for 28 days.



Follow these instructions carefully. Consult your doctor or pharmacist if there is anything you do not understand.

### If you use more Dropodex Eye Drops than you should

If you put too much Dropodex into your eye(s), close your eyes and rinse off any excess with warm water. If the contents of Dropodex are accidentally swallowed, tell your doctor **immediately** or go to your nearest hospital casualty department. Take your medicine with you.

#### **If you forget to use Dropodex Eye Drops**

Do **not** use a double dose to make up for a forgotten dose. If you forget to use a dose of Dropodex, use it as soon as you remember and then carry on as before.

#### **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 unwanted side effects. Occasionally this medicine may cause temporary stinging, burning, redness or watering of the eyes.

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.

Topical corticosteroids should not be used for longer than one week except under ophthalmic supervision. You should consult your doctor if you become aware of any changes in your eyesight.

It is possible that some of the solution may be absorbed into the general circulation of the body following administration to the eye. It is unlikely, however, that this will have any unwanted effect on the body because so little of the eye drop is absorbed through the eye. The action of pressing on the inner part of the eye when adding the drops will also help to reduce this absorption even further. If it does happen, it can cause 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").

#### **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:

#### **Malta**

ADR Reporting

Website: [www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal)

#### **United Kingdom**

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 Dropodex 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 sachet, single-dose containers and on the carton. The expiry date can be found after 'EXP'. The expiry date refers to the last day of that month.

Store in original package. After opening the sachet, the unopened ampoules can be stored for 28 days. Do not store above 25°C. Do not refrigerate or freeze.

The Dropodex single-dose container 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 Dropodex Eye Drops contain**

The active substance is dexamethasone sodium phosphate.  
The other ingredients are: sodium chloride, disodium edetate, disodium phosphate dodecahydrate (E339) and purified water.

### **What Dropodex Eye Drops look like and contents of the pack**

Each single-dose container contains 0.4 ml Dropodex Eye Drops, solution without preservative. There are five single-dose containers per sachet. Each carton contains four sachets.

Each individual single-dose container contains 0.4 mg of dexamethasone phosphate (as dexamethasone sodium phosphate) in 0.4 ml of solution.

### **Marketing Authorisation Holder and Manufacturer:**

#### Marketing Authorisation Holder:

Rayner Pharmaceuticals Limited,  
10 Dominion Way, Worthing,  
West Sussex, BN14 8AQ,  
United Kingdom.  
Tel: +44 (0) 1903 258 900

#### Manufacturer:

Unolab Manufacturing S.L.  
Avda. De. Las Flores, 6  
Humanes De Madrid,  
28970 Spain

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