

# 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® is and what it is 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® is and what it is 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 medicines 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®

### Do not use Dropodex®:

- 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 of the eye.
- 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 before using Dropodex®:

- If you have an eye infection or ulcer.
- 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®. 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 experience blurred vision or other visual disturbances.
- 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

Do not give this medicine to children less than 2 years due to a lack of data on safety and efficacy in this age group.

Use of Dropodex® in children and adolescents must be restricted. In children, continuous, long term use of corticosteroid eye drops should be avoided.

### Other medicines and Dropodex®

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. Eye ointments should be applied last.

### 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 pharmacist 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.

### 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.

### Dropodex® contains phosphates

This medicine contains 1.01 mg phosphates in each 0.4 mL dose which is equivalent to 2.52 mg/mL phosphates (from 9.5 mg/mL disodium phosphate dodecahydrate). 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 Dropodex®

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist 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.

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®:

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.



(Figure 1)



(Figure 2)



(Figure 3)



(Figure 4)

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

### If you use more Dropodex® 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®

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

### If you stop using Dropodex®

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 medicine, ask your doctor or pharmacist.

## 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.

### Hormone conditions

Frequency not known:

- Hormone problems (Cushing's syndrome): 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 (see section 2, "Warnings and precautions").

These hormone conditions may occur as it is possible that some of the Dropodex solution may be absorbed into the general circulation of the body after they are put into the eye. It is unlikely, however, that this will have any unwanted effect on the body because so little of the eye drops are 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.

### Eye conditions

Very common:

- High pressure in the eye after 2 weeks of using the drops (raised intraocular pressure)

Common (these side effects, which can occur after instillation of Dropodex, are usually mild and do not last long):

- Discomfort
- Irritation
- Burning
- Itching

Uncommon:

- Signs of an allergic reaction
- Healing which takes longer than expected
- Cloudy lens (cataract)
- Infections
- High pressure in the eye (glaucoma)
- Blurred vision

Very rare:

- Inflamed surface of the eye giving red eye, tears and irritation (conjunctivitis)
- Swelling of the eyelid (eyelid oedema)
- Inflammation of the eye which causes pain and redness (uveitis)
- Settling of calcium on the surface of the eye (corneal calcification)
- Inflamed surface of the eye causing blurred vision, dry eyes, sensitivity to light, burning, tears and a sandy sensation in your eye (keratitis)
- Thinning of the surface of the eye (corneal thinning)
- Swelling of the surface of the eye (corneal oedema)
- Ulcer on the surface of the eye causing pain, tears, squinting and vision loss (corneal ulceration)
- Small holes on the surface of the eye (corneal perforation)

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.

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.

### 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 Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Dropodex®

**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 carton after 'EXP'. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not refrigerate or freeze.

Store in original package. After opening the sachet, the unopened ampoules can be stored for 28 days.

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® contains

- The active substance is dexamethasone sodium phosphate.
- The other ingredients are: sodium chloride, disodium edetate, disodium phosphate dodecahydrate (E339) and purified water (see Section 2, "Dropodex® contains phosphates").

### 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.  
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#### Manufacturer:

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For large print, audio or braille versions contact the RNIB on the Medicine Leaflet Line 0800 198 5000.

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