

Package leaflet: Information for the user

Dexamethasone Phosphate 1mg/ml (as sodium phosphate) Eye Drops, Solution in a single-dose container

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.

The name of your medicine is Dexamethasone Phosphate 1mg/ml (as sodium phosphate) Eye Drops, Solution in a single-dose container. Throughout the rest of this leaflet it is referred to as Dexamethasone Phosphate Eye Drops.

What is in this leaflet:

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

1. What Dexamethasone Phosphate Eye Drops are and what it is used for

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

Dexamethasone Phosphate Eye Drops is used to treat inflammation of your eyes.

If you have an infected eye (red eye, tears and mucus), you will be given another medicine to take at the same time as Dexamethasone Phosphate Eye Drops. See Section 2.

2. What you need to know before you use Dexamethasone Phosphate Eye Drops

Do not use Dexamethasone Phosphate Eye Drops

- if you are suffering from an eye infection that you are not using a medicine for
- 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
- if you are allergic (hypersensitive) to dexamethasone phosphate, or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

DO NOT INJECT, DO NOT SWALLOW.

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

Talk to your doctor, pharmacist or nurse before using Dexamethasone Phosphate Eye Drops if the following apply to you, as close monitoring is needed:

- for 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 (e.g. herpes). Only use Dexamethasone Phosphate 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 Phosphate 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 Phosphate 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 Phosphate Eye Drops for a short period of time.
- If you are diabetic, tell your ophthalmologist or optician that you are using Dexamethasone Phosphate Eye Drops.

- If you have a red eye that has not been diagnosed, do not use Dexamethasone Phosphate Eye Drops.
- If you usually wear contact lenses: avoid wearing contact lenses while you are using Dexamethasone Phosphate 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 Phosphate 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.

Other medicines and Dexamethasone Phosphate Eye Drops

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

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

- Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
- Some medicines may increase the effects of Dexamethasone Phosphate Eye Drops and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

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

Pregnancy and breast feeding

There is not enough information on the use of Dexamethasone Phosphate Eye Drops during pregnancy to know the possible side effects.

For this reason, the use of Dexamethasone Phosphate Eye Drops during pregnancy is not recommended.

It is not known if this medicine is present in breast milk. However, the dose of Dexamethasone Phosphate Eye Drops is low. Dexamethasone Phosphate Eye Drops 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.

3. How to use Dexamethasone Phosphate Eye Drops

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

- 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

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 Phosphate 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 Phosphate Eye Drops

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

If you stop using Dexamethasone Phosphate Eye Drops

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, pharmacist or nurse.

4. Possible side effects

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

Hormone problems:

Not known: frequency cannot be estimated from the available data

- 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):

- 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
- changes in the thickness of the surface of the eye,
- ulcer on the surface of the eye causing pain, watering, redness, and vision loss,
- perforation of the surface of the eye (the cornea).

General conditions:

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

- if used for prolonged periods, the production of certain hormones may be reduced. Signs of this could include low blood sugar, dehydration, weight loss and feeling confused about where you are.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting systems listed below:

United Kingdom:

Yellow Card Scheme

Website: <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; 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 Dexamethasone Phosphate 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 single-dose container after EXP. The expiry date refers to the last day of that month. Do not store above 25°C. Store in the original package. Keep the single-dose containers in their sachet to protect them from light.

After first opening the sachet, use the single-dose containers within 28 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 any medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Dexamethasone Phosphate Eye Drops looks like and contents of the pack

Each single-dose unit contains 0.4 ml Dexamethasone Phosphate Eye Drops, solution without preservative. There are five single-dose units per sachet. Each carton contains four sachets.

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

Dexamethasone Phosphate Eye Drops, solution also contain sodium chloride, disodium edetate, disodium phosphate dodecahydrate (E339) and purified water.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK

Manufacturer

Novocat Farma S.A, Avda de la Flores, Barcelona, Spain.

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only).

Please be ready to give the following information:

Product name	Reference number
Dexamethasone Phosphate 1mg/ml (as sodium phosphate) Eye Drops, Solution in a single-dose container	PL 29831/0589

This is a service provided by the Royal National Institute of Blind People.

For patients in the Republic of Ireland please call +44 1978 669272

This leaflet was last revised in 01/2017

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

UK & Ireland: Dexamethasone Phosphate 1mg/ml (as sodium phosphate) Eye Drops, Solution in a single-dose container