

1mg/ml eye drops, solution

dexamethasone phosphate

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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.

Important information about the administration of this product

Eythalm Eye Drops are contained within a novel multi-dose eye drop bottle, which allows for the solution not to contain any preservatives. Due to the design of the container, administration with these eye drops is not the same as standard eye drop bottles.

- Prior to first use, practice using the drops away from the eye. Slowly squeeze the bottle to deliver one drop in the air to get used to the pressure and time required to deliver one drop.
- Please note that there might be a few seconds delay between squeezing and the drop coming out. Do not squeeze too hard, or more than one drop may come out.
- After use and prior to recapping, the bottle should be shaken once in a downwards direction, without touching the dropper tip, in order to remove any residual liquid on the tip. This is necessary in order to ensure delivery of subsequent drops.
- If more than one type of eye drop is used, leave at least 15 minutes between administration of each eye drop solution.

Please read the full instructions on the correct use of this product in **Section 3** of the leaflet ("How to use Eythalm"), before using these eye drops.

What is in this leaflet

- 1.What Eythalm is and what it is used for

- 2.What you need to know before you use Eythalm

- 3.How to use Eythalm

- 4.Possible side effects

- 5.How to store Eythalm

- 6.Contents of the pack and other information

1. What Eythalm is and what it is used for

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

Eythalm 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 Eythalm. See Section 2.

Eythalm eye drops solution is a sterile solution that does not contain a preservative.

2. What you need to know before you use Eythalm

Do not use Eythalm:

- if you are allergic to dexamethasone phosphate or any of the other ingredients of this medicine (listed in section 6).

- 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 glucocorticoids (family of corticosteroid medicines).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Eythalm.

- 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 Eythalm and in particular:

- for children and the elderly. More frequent monitoring is advised.

- if you have an eye infection. Only use Eythalm 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 Eythalm, 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 Eythalm.

- if you have glaucoma, a condition which can cause damage to the optic nerve and may cause loss of sight.

- At the first sign of corneal calcification the drug should be withdrawn and the patient should be switched to a phosphate-free preparation.

- 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 Eythalm 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 Eythalm.

- Contact lenses: do not wear contact lenses when you are using Eythalm.

If you have a history of contact hypersensitivity to silver, you should not use this product.

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 Eythalm. Talk to your doctor before stopping the treatment by yourself.

These risks are especially important in children and patients treated with a medicine called ritonavir or cobicistat.

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

Other medicines and Eythalm

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 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 cause settling of calcium phosphate 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 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 using this medicine.

There is not enough information on the use of dexamethasone during pregnancy to know the possible side effects. For this reason, the use of Eythalm during pregnancy is not recommended.

It is not known if this medicine is present in breast milk. However, the dose of Eythalm is low. Eythalm can be used when breast-feeding.

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.

Eythalm contains phosphate buffer

This medicine contains 1.976mg phosphates in each ml of solution, which is equivalent to 7,450mg 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 Eythalm

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

The recommended 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.

Elderly

There is no need to adjust the dose.

Use in children

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

Method of administration

Ocular use: this medicine is an eye drop to be used in the eye.

Do not allow the tip of the multi-dose container to touch the eye or areas around the eye. It could cause injury to your eye. The eye drops solution may become contaminated with bacteria that can cause eye infections leading to serious damage of the eye, even loss of vision.

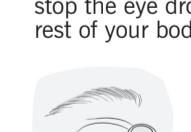
To avoid possible contamination of the multi-dose container, keep the tip of the multi-dose container away from contact with any surface.

Before instillation of the eye drops:

- Wash your hands before opening the bottle.
- Do not use this medicine if you notice that the tamper-proof seal on the bottle neck is broken before you first use it.
- When using for the first time, before delivering a drop to the eye, you should first of all practice using the dropper bottle by squeezing it slowly to deliver one drop into the air, away from the eye.
- When you are confident that you can deliver one drop at a time, choose the position that you find most comfortable for the instillation of the drops (you can sit down, lie on your back, or stand in front of a mirror).

Instillation:

- 1.Hold the bottle directly below the cap and turn the cap to open the bottle.



Do not touch anything with the tip of the bottle to avoid contamination of the solution.

- 2.Tilt your head backwards and hold the bottle above your eye.

3.Pull the lower eyelid down and look up. Squeeze the bottle gently in the middle and let a drop fall into your eye. Please note that there might be a few seconds delay between squeezing and the drop coming out.

Do not squeeze too hard. If you are not sure how to administer your medicine, ask your doctor, pharmacist or nurse.



- 4.Blink a few times so that the drop spreads over the eye.



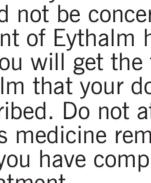
5.After using Eythalm, press a finger into the corner of your eye, by the nose for a few minutes. This helps to stop the eye drops getting into the rest of your body.



- 6.Repeat the instructions 2 – 5 to deliver a drop into the other eye also, if your doctor has instructed you to do this. Sometimes only one eye needs to be treated and your doctor will advise if this applies to you and which eye needs treatment.

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- After use and prior to recapping, the bottle should be shaken once in a downwards direction, without touching the dropper tip, in order to remove any residual liquid on the tip. This is necessary in order to ensure delivery of subsequent drops.



After you have used all doses there will be some Eythalm left in the bottle. You should not be concerned since an extra amount of Eythalm has been added and you will get the full amount of Eythalm that your doctor has prescribed. Do not attempt to use the excess medicine remaining in the bottle after you have completed the course of treatment.

Frequency of use

4 to 6 times a day.

Duration of treatment

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

If you use more Eythalm 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 Eythalm

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

If you stop using Eythalm

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.

Endocrine disorders:

Not known (frequency 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").

Eye disorders:

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

- High pressure in the eye after 2 weeks of using the drops.

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):

- Signs of an allergic reaction.

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

- Inflamed surface of the eye giving red eye, tears and irritation (conjunctivitis).

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 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 Eythalm

Keep this medicine out of the sight and reach of children.

Do not use the eye drops for longer than 28 days after first opening the bottle. Write down the date you opened the bottle in the space on the bottle label and box.

Do not use this medicine after the expiry date which is stated on the carton and bottle after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Eythalm contains

- The active substance is dexamethasone phosphate. Each millilitre of solution contains 1mg of dexamethasone phosphate as dexamethasone sodium phosphate.
- The other ingredients are disodium phosphate dodecahydrate, sodium chloride, disodium edetate, hydrochloric acid (for pH adjustment), sodium hydroxide (for pH adjustment) and water for injections.

What Eythalm looks like and contents of the pack

Eythalm eye drops, solution is presented as a 6ml clear solution in a white opaque 11ml LDPE bottle with white Novelia nozzle (HDPE and silicone) and a white HDPE cap. Each carton contains 1 or 3 bottles. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Aspire Pharma Ltd

Unit 4, Rotherbrook Court

Bedford Road, Petersfield

Hampshire, GU32 3QG, UK

Manufacturer

Pharmathen S.A., 6 Dervenakion

15351 Pallini Attiki, Greece

Or

EXCELVISION 27 st. La Lombardière,

ZI La Lombardière, ANNONAY 07100,

France

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