

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.
 - The medicine will be called Dexamethasone sodium Phosphate Eye drops BP in this leaflet.

What is in this leaflet

1. What Dexamethasone Sodium Phosphate Ophthalmic Solution USP are and what they are used for
2. What you need to know before you use your eye drops
3. How to use your eye drops
4. Possible side effects
5. How to store your eye drops
6. Contents of the pack and other information

1. What Dexamethasone Sodium Phosphate Ophthalmic Solution USP is and what it is used for
Dexamethasone Sodium Phosphate Ophthalmic Solution USP contains a corticosteroid. It is used to treat inflamed eyes (red and painful). The part of the eye affected will vary depending on the cause of the inflammation. Your doctor may sometimes prescribe other drugs at the same time to make sure that the inflammation is treated effectively. This medicine is indicated for children, adults and the elderly.

2. What you need to know before you use Dexamethasone Sodium Phosphate Ophthalmic Solution USP

Do not use Dexamethasone Sodium Phosphate Ophthalmic Solution USP

- you are allergic to the active substance (dexamethasone sodium phosphate) or any of the other

ingredients of this medicine

- you have high pressure inside the eye or you are at risk of developing glaucoma. Your doctor will have checked for this.
- you currently have conditions affecting your cornea.
- it is intended for long term continuous therapy in children (at the discretion of the physician).

Warning and precautions

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 longterm or intensive treatment with Dexamethasone Sodium Phosphate. 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 blurred vision or other visual disturbances. Children In children, continuous, long term use of these eye drops should be avoided. Check with your doctor if your child has been using this medicine for a long time. The doctor or eye specialist may decide to prescribe an alternative. Other medicines and your eye drops Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Dexamethasone Sodium Phosphate can increase the effects of:

- medicine used to treat epilepsy (barbiturates)
- medicine used to help you sleep or to relieve anxiety (sedative hypnotics)
- medicine used to treat depression (tricyclic antidepressants). Dexamethasone Sodium Phosphate Eye Drops BP® Dexamethasone Sodium Phosphate can decrease the effects of:

- medicines such as anticholinesterases (indicated for reduced intestinal movement and for myasthenia gravis (a muscle weakening disease).
- medicines used to treat infection of the eye caused by a virus
- medicines similar to aspirin called salicylates (indicated for inflammation, pain, fever and blood thinning).

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

Tell your doctor or eye specialist, he/she may decide to use these drops or to prescribe you an alternative.

Contact lenses

Your doctor will ask you to remove your contact lenses prior to the administration of the drops. There is no information on the effect of this product on contact lenses. Therefore do not wear contact lenses until the effects of the drops have completely worn off.

Driving and using machines

As with all eye drops, your vision may be blurred after putting the drops in. Wait until your vision is clear before driving or using machines.

Dexamethasone Sodium Phosphate contains sodium dihydrogen phosphate dihydrate and disodium phosphate. This medicine contains 0.16mg phosphates in each drop which is the equivalent of 3.95mg/ml. If you suffer from severe damage to the clear layer at the front (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 Dexamethasone sodium phosphate Ophthalmic Solution USP

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

The drops are for single use only and provided in single use Dexamethasone Sodium Phosphate Ophthalmic Solution USP units, to treat both eyes if necessary. Once opened, use immediately.

Discard any unused portion

Dosage • The normal adult dose is 1 to 2 drops in one or both eyes as often as directed by your doctor.

- The dose for children will be decided by the doctor or eye specialist.

Method of administration

If you are putting the eye drops in yourself, then follow these instructions carefully:

1. Wash your hands.
2. Use a mirror, this will help you to see what you are doing.
3. Carefully dry your eyes using a tissue. Twist and pull cap to separate from the Dexamethasone Sodium Phosphate Ophthalmic Solution USP body (Diagram 1).
4. Pull your lower eyelid down gently, and then carefully place 1 or 2 drops inside your lower eyelid.

Make sure the dropper does not touch any parts of your eye.

5. Close your eye and blink a few times to make sure your eye is covered by the liquid.
6. Close the eyelids. It is advisable to press gently on the inner corner of your eyelid for 3 minutes. This will help stop the solution draining into your nose and throat. This is especially advisable in children, the elderly and population at risk.
7. Repeat steps 4, 5 and 6 for the other eye if necessary, then throw away the Dexamethasone Sodium Phosphate Eye Drops BP unit, even if some solution remains.

If your eyes get worse or are not better after a few weeks of using the eye drops, see your doctor or eye specialist or pharmacist. This medicine should not be used for long term and frequent use without talking to your doctor or pharmacist.

If you use more Dexamethasone Sodium Phosphate than you should, an overdose is very unlikely to occur. If you suddenly feel unwell after using the drops, tell your doctor or eye specialist or contact the nearest emergency department immediately.

If you forget to use Dexamethasone Sodium Phosphate, you should take the missed dose as soon as you remember, unless it is nearly time for the next dose, but you should not take a double dose to make up for a missed dose.

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 side effects.

- Dexamethasone Sodium Phosphate may sting when the drops are first put in.
- Frequency not known: Blurred vision.
- 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.
- Long term, frequent use of corticosteroids can lead to clouding of the lens in the eye (cataract) or to an increase of the pressure inside the eye.
- 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”). Consult your doctor if you feel any changes in your eyesight. If any of the side effects gets serious, please seek immediate medical attention. If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Dexamethasone sodium phosphate Ophthalmic Solution USP

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 the letters “EXP”.

The expiry date refers to the last day of that month.

Do not store above 30°C. Do not freeze. Store in original package in order to protect from light. The drops are for single use only and provided in single use Dexamethasone Sodium Phosphate Ophthalmic Solution USP units, to treat both eyes if necessary. Once opened, use immediately.

Discard any unused portion.

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 pack and other information

What do your eye drops contain

- The active substance is dexamethasone sodium phosphate. Each Dexamethasone Sodium Phosphate Ophthalmic Solution USP unit contains approximately 0.5 ml eye drops solution of dexamethasone sodium phosphate 0.1% w/v (0.5 mg).
- The other ingredients are disodium edetate, sodium dihydrogen phosphate dihydrate, anhydrous disodium hydrogen phosphate and purified water. This medicine does not contain a preservative as it is a sterile single use unit.

What your eye drops look like and contents of the pack

Your eye drops are a colourless solution. Each carton contains 1 unit.

Dexamethasone Sodium Phosphate Ophthalmic Solution USP



Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Merit Organics Ltd

509, 5th Floor, Western Edge I,

Western Express Highway

Borivali East

Mumbai - 400 066

India

Manufacturer

Merit Organics Ltd

509, 5th Floor, Western Edge I,

Western Express Highway

Borivali East

Mumbai - 400 066

India

The leaflet does not contain all the information about your medicine. If you have any questions ask your doctor or pharmacist.