



Betamethasone 0.1% w/v Drops

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

1. What Betamethasone Drops are and what they are used for

Betamethasone Drops contain Betamethasone Sodium Phosphate which belongs to a group of medicines called corticosteroids. These are used to relieve redness and swelling. Betamethasone Drops are used to treat redness and swelling of the eyes, nose and ears.

2. What you need to know before you use Betamethasone Drops

Do not use Betamethasone Drops if you are:

- allergic (hypersensitive) to Betamethasone Sodium Phosphate or to any of the other ingredients of this medicine (listed in section 6).

Do not use in your eyes if you:

- have a viral infection of the eye
- have a fungal infection of the eye
- have tuberculosis of the eye
- have an eye infection that is producing pus
- suffer from raised pressure in your eye(s) (glaucoma)
- suffer from herpes in your eye(s)
- have undiagnosed red eye(s)
- are wearing soft contact lenses. These should be removed whilst you are using Betamethasone Drops.

Do not use in your ears if you have:

- a hole in your ear drum

If any of the above apply please tell your doctor or pharmacist.

Take special care with Betamethasone Drops:

- Do not use Betamethasone Drops for a prolonged period of time (more than 7 days) as this may cause serious side effects, particularly in children. (see section 4 of this leaflet)
- You should be aware that if you are using Betamethasone Drops in your eyes your doctor may need to check your eyes frequently during your treatment
- if the patient has an untreated nasal infection, has pulmonary tuberculosis or after nasal surgery.

Other medicines and Betamethasone Drops

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, before you use this medicine.

If you have any doubts about whether this medicine is suitable for you, consult your doctor or pharmacist.

Pregnancy and breast-feeding

This medicine should be avoided if you are pregnant, trying to become pregnant or breastfeeding, unless your doctor has recommended it.

Driving and using machines

Betamethasone Drops can cause temporary blurring of vision after application to the eye. Wait until your vision is clear whilst driving or using machines.

Betamethasone Drops contains benzalkonium chloride

Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards. Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

3. How to use Betamethasone Drops

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

How much to use

For adults, the elderly and children

For use in the eye:

The usual starting dose is one or two drops to be put into the eye every two hours. Your doctor may reduce the dose once the condition of your eye has begun to improve.

For use in the ear:

The usual starting dose is two or three drops put into the ear every three to four hours. Your doctor may reduce the dose once the condition of your ear has begun to improve.

For use in the nose:

The usual dose is two or three drops into each nostril twice daily or as required.

Instructions for use

Instructions for use in the eye:

If you wear soft contact lenses these must be removed during treatment of the eyes with Betamethasone Drops.

1. Before opening a new bottle of Betamethasone Drops, please check that the safety strip on the bottom of the outer cap is unbroken.
2. Twist the outer cap to break the seal.
3. After cap is removed, if the tamper evident snap collar is loose, please remove before using the product. Take care not to touch the end of the nozzle.
4. Wash your hands well before use.
5. If you are putting in the drops yourself you should use a mirror.
6. Tilt your head back and look up at the ceiling.
7. Pull the lower lid of the eye out to form a small pocket between your eyelid and your eye.
8. Hold the container between the thumb and middle finger of the other hand, turn the bottle upside down near to your eye, try not to touch your eye with the nozzle.
9. Apply enough pressure to the container to release one to two drops, or as directed by your doctor.
10. Blink your eye a few times.
11. If you think that you have missed your eye, then insert another drop
12. Repeat steps 5-10 in the other eye, if you have been told to use Betamethasone Drops in both eyes.
13. Replace the outer cap on the bottle, trying not to touch the applicator tip with anything, including the eye or your fingers
14. Wash your hands

Continued overleaf

Instructions for use in the ear

1. Wash your hands well before use
2. Remove the outer cap on the bottle
3. Insert the nozzle into the affected ear and apply drops as advised by your doctor
4. Repeat steps 1-3 in the other ear, if you have been told to use Betamethasone Drops in both ears
5. Replace the outer cap on the bottle, trying not to touch the applicator tip with anything, including your fingers
6. Wash your hands

Instructions for use in the nose

1. Wash your hands well before use
2. Remove the outer cap on the bottle
3. Tilt your head back and pour into each nostril drop by drop
4. Replace the outer cap on the bottle, trying not to touch the applicator tip with anything, including your fingers
5. Wash your hands

- If there is no improvement in your symptoms after 7 days, stop using the drops and see your doctor again.
- Discard 4 weeks after opening

If you are unsure about how to use Betamethasone Drops talk to your doctor or pharmacist.

If you use more Betamethasone Drops than you should

If you are at all concerned that you have used too much of this medicine contact your doctor or pharmacist.

Betamethasone Drops are for external use only. If you have swallowed or you suspect someone else has swallowed any, contact your doctor or pharmacist.

If you forget to use Betamethasone Drops

If you have just missed using your dose and it is a long time until your next dose is due, put in the missed dose now and continue the course of treatment. If it is near the time for using your next dose wait and use this dose at the correct time.

Do not take a double dose to make up for one you have missed.

If you stop using Betamethasone Drops

You should keep using Betamethasone Drops for as long as your doctor has instructed. Your treatment is helping your condition, even if you have not noticed a difference in how you feel. Should you need to stop your treatment, your doctor will advise you how to do this.

4. Possible side effects

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

If you experience any of the following side effects you should tell your doctor **immediately**. These are symptoms of an allergic reaction.

- difficulty in breathing with or without swelling of the face, lips, tongue and/or throat
- swelling of the face, lips tongue and/or throat, which may cause difficulty in swallowing
- severe itching of the skin (with raised lumps).

Other possible side effects include:

- irritation, burning, itching and stinging in the area. This may occur after treatment has stopped.
- raised pressure in the eye (only when used in the eye)
- pupil dilation, drooping of the eyelid, corneal inflammation, sneezing, headache, light headedness, nausea, nosebleeds, rebound congestion, nasal discomfort, disturbance to sense of smell, disturbance to sense of taste, stunted growth in children

Where you suffer from a disease (other than that for which you are using Betamethasone Drops) that causes thinning of the surface of the eye, serious damage may be caused.

Prolonged use of this medicine (for more than 7 days) can lead to cloudiness of the lens of the eye (cataracts), it is therefore advised that the lens of the eye is checked frequently during use of this medicine.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. 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 on the MHRA website www.mhra.gov.uk/yellowcard. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Betamethasone Drops

Keep this medicine out of the sight and reach of children. Make sure the container is properly closed after each use. Store Betamethasone Drops in the original container away from direct light. Store below 25°C.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month. Dispose of this medicine 4 weeks after opening

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. Content of the pack and other information.

What Betamethasone Drops contain

The active substance is betamethasone sodium phosphate 0.1%w/v
The other ingredients are benzalkonium chloride solution, disodium edetate, sodium phosphate and purified water.

What Betamethasone Drops look like and contents of the pack

Betamethasone Drops are a clear, colourless and sterile solution supplied in a plastic dropper bottle with a cap. Each bottle contains 5 or 10ml of the solution.

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If you would like any more information, or would like the leaflet in a different format, please contact Medical Information at the above address.

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