

Vistamethasone Drops™

Betamethasone Sodium Phosphate

Read all of this leaflet carefully before you start using this medicine. It contains important information.

- 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. Do not pass it on to others. It may harm them, even
- if their symptoms are the same as yours.
 If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

- 1. What Vistamethasone Drops are and what they are used for
- 2. Before you use Vistamethasone Drops
- 3. How to use Vistamethasone Drops
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1. What Vistamethasone Drops are and what they are used for

Vistamethasone Drops contain Betamethasone Sodium Phosphate which belongs to a group of medicines called corticosteroids. These are used relieve redness and swelling.

Vistamethasone Drops are used to treat redness and swelling of the eyes, nose and ears.

2. Before you use Vistamethasone Drops

Do not use Vistamethasone Drops if you are:

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

Do not use in your eyes if you:

- have a viral infection of the eye
- have a fungal infection of the eye
 have tuberful size 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 Vistamethasone 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 Vistamethasone Drops:

- Do not use Vistamethasone 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 Vistamethasone Drops in your eyes your doctor may need to check your eyes frequently during your treatment.

Taking other medicines

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 breast-feeding, unless your doctor has recommended it

Driving and using machines

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

Important information about some of the ingredients of Vistamethasone Drops

 Vistamethasone Drops contain benzalkonium chloride which is known to discolour soft contact lenses and may cause eye irritation. If you usually wear soft contact lenses they should be removed before you use Vistamethasone Drops.

3. How to use Vistamethasone Drops

Always use Vistamethasone Drops exactly as your doctor has told you. You should 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 Vistamethasone Drops.

- Before opening a new bottle of Vistamethasone 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. Wash your hands well before use.
- Remove the outer cap. If you are putting in the drops yourself you should use a mirror.
- 5. Tilt your head back and look up at the ceiling.
- Pull the lower lid of the eye out to form a small pocket between your eyelid and your eye.
- 7. 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
- Ápply enough pressure to the container to release one to two drops, or as directed by your doctor.
- Blink your eye a few times.

your eye with the nozzle.

- If you think that you have missed your eye, then insert another drop
- Repeat steps 5-10 in the other eye, if you have been told to use Vistamethasone Drops in both eyes.
- Replace the outer cap on the bottle, trying not to touch the applicator tip with anything, including the eye or your fingers
- 13. Wash your hands

Continued overleaf

Instructions for use in the ear

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

Instructions for use in the nose

- . Wash your hands well before use
- 2. Remove the outer cap on the bottle
- Tilt your head back and pour into each nostril drop by drop
- Replace the outer cap on the bottle, trying not to touch the applicator tip with anything, including your fingers
- 5. Wash your hands
- Do not use for longer than 7 days
- Discard 4 weeks after opening

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

If you use more Vistamethasone Drops than you should

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

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

If you forget to use Vistamethasone 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 Vistamethasone Drops

You should keep using Vistamethasone 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, Vistamethasone Drops 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)

Where you suffer from a disease (other than that for which you are using Vistamethasone 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.

5. How to store Vistamethasone Drops

Keep this medicine out of the sight and reach of

Make sure the container is properly closed after each use.

Store Vistamethasone Drops in the original container away from direct light.
Store below 25°C.

Do not use Vistamethasone Drops 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

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further Information

What Vistamethasone 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 Vistamethasone Drops look like and contents of the pack

Vistamethasone 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

Marketing Authorisation Holder:

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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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