

Patient Information Leaflet: Betnesol-N 0.1% w/v, 3500 IU/ml Eye, Ear and Nasal Drops, solution. Betamethasone Sodium Phosphate and Neomycin Sulphate.

**Betnesol-N 0.1% w/v, 3500 IU/ml Eye, Ear and Nasal Drops, solution.
Betamethasone Sodium Phosphate and Neomycin Sulphate.**

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.
- In this leaflet, Betnesol-N Eye, Ear & Nose Drops will be called Betnesol-N Drops.

What is in this leaflet:

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

1. What Betnesol-N Drops is and what it is used for

Betnesol-N Drops belongs to a group of medicines called topical corticosteroids ('steroids' for short). Betnesol-N Drops work by reducing inflammation (redness, itching and soreness). Topical means that they are used on the outside of the body and not taken by mouth or injection. Betnesol-N Drops also contain neomycin sulphate, an aminoglycoside antibiotic, which prevents bacterial infection developing. Betnesol-N Drops is used to treat inflammation of the eye, ear or nose when there may also be a risk of bacterial infection.

It is important to use this medicine to prevent any damage to the delicate tissues of your eyes, ear or nose and to prevent any infection developing.

2. What you need to know before you use Betnesol-N Drops

Important: Never use this medicine in your eye without first checking with your doctor. If it is used for the wrong condition, it could lead to blindness.

Do not use Betnesol-N Drops if:

- You are allergic to betamethasone
- You are allergic to any of the other ingredients of Betnesol-N Drops (listed in section 6)
- You have not checked your eye condition with your doctor first. If this medicine is used in your eye, for the wrong condition, it could lead to blindness.
- You have an infection in the eye, or it is producing pus and is sticky
- You have an infection in the ear or nose
- You have ulcers in your eye (shingles)
- You have glaucoma (increased pressure in the eye)
- You have a perforated ear drum.

If any of the above applies to you talk to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before using this medicine if:

- You know you have (or think you have) a mitochondrial disease (mutations in the parts of your cells which help make energy); certain mitochondrial diseases may increase your risk of hearing loss with this product.

- You wear soft contact lenses

- You have been treated with Betnesol-N drops or similar corticosteroid medicine recently. You should not use corticosteroids for a long time without regular medical check-ups from your doctor

- You have redness in your eyes for which you do not know the cause. Steroid treatment must not be given unless the cause of the redness is known

- You have an infection of the lining of your nose, which is not being treated

- You have recently had surgery on your nose which has not yet healed

- You have tuberculosis (TB)

- You have thinning of the cornea or sclera (the tissues which cover the outer surface of the eye)

Using these drops could lead to a hole in the eyeball

- You are giving this medicine to an infant. Prolonged use in babies may cause the adrenal gland to stop working properly

- You are applying these drops to open wounds or damaged skin. The antibiotic component can cause permanent, partial or total deafness if used on open wounds or damaged skin. This possibility should be borne in mind if high doses are given to small children or infants.

If any of the above applies to you talk to your doctor or pharmacist.

Other medicines and Betnesol-N Drops

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 Betnesol-N Drops and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat)

Pregnancy and breast-feeding

If you are pregnant, trying to become pregnant or breast-feeding ask your doctor or pharmacist for advice before using Betnesol-N Drops. If you use these drops while pregnant there may be small risk of damage to the ear, cleft palate or retarded growth in the foetus.

Driving and using machines

Betnesol-N Drops may cause temporary blurred vision and lightheadedness. If this happens to you, do not drive or use machinery until you return to normal.

Betnesol-N Drops contains Benzalkonium Chloride

This medicine contains 0.01% w/v benzalkonium chloride in each dose. 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. Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time.

Betnesol-N Drops contains Sodium Dihydrogen Phosphate Dihydrate and Disodium Phosphate Anhydrous

This medicine contains 0.23% w/v phosphates in each dose. 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.

Warnings about visual problems when using Betnesol-N Drops

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

3. How to use Betnesol-N Drops

Important:

Your doctor will choose the dose that is right for you. Your dose will be shown clearly on the label that your pharmacist puts on your medicine. If it does not, or you are not sure, ask your doctor or pharmacist.

Things to remember about your dose:

- Always use Betnesol-N exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
- How often you use the drops will depend on how your body responds to the treatment
- Use as few drops as possible for the shortest possible time.

Getting ready to use your medicine

Check that the seal on the bottle is not broken before using Betnesol-N Drops for the first time. Wash and dry your hands.

Do not breathe on or touch the dropper nozzle and do not touch the eyes, ear or nose with the dropper nozzle.

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

Using your medicine

Eyes

- The usual dose is 1 or 2 drops put into the eye up to 6 times each day
 - Once the redness, itching and soreness starts to feel better, apply the drops less often.
1. Tilt the head back
 2. Gently pull lower eyelid downwards and outwards
 3. Place drops in the gap between the lid and eye (squeeze bottle very gently if necessary)
 4. Blink a few times to spread out the drops
 5. Repeat for the other eye if needed.

Medical check-ups

If you are using this medicine for your eyes and you use it for a number of weeks, your doctor may ask you to have check-ups.

These are to make sure that your medicine is working properly and that the dose you are taking is right for you. Your doctor will check your eyes for:

1. An increase in pressure
2. Cataracts
3. Infection

Ears

- The usual dose is 2 or 3 drops put into the ear three or four times each day
 - Once the redness, itching and soreness starts to feel better, apply the drops less often.
1. Tilt the head to one side
 2. Place drops in the ear canal (squeeze bottle gently if necessary)
 3. Keep head tilted for a minute or two to let the drops soak in
 4. Repeat for other ear if needed.

Nose

The usual dose is 2 or 3 drops put into each nostril two or three times each day.

1. Tilt head backwards
2. Place drops in nostril (squeeze bottle gently if necessary)
3. Keep head tilted and sniff gently to let the drops soak in
4. Repeat for other nostril if needed.

Medical check-ups

Your doctor will regularly check the growth of children who are taking Betnesol-N by nose over a long period of time.

If you use more Betnesol-N Drops than you should

If you accidentally use too much Betnesol-N Drops it is unlikely to lead to any serious side effects. However, if you are concerned, contact the nearest hospital casualty department or your doctor.

Accidental swallowing of the contents of one bottle (up to 10 ml) is unlikely to lead to any serious adverse events.

It is important that you take your dose as stated on the pharmacist's label or advised by your doctor. You should use only as much as your doctor recommends; using more or less may make your symptoms worse.

If you forget to use Betnesol-N

Do not use a double dose to make up for a missed dose. Simply use the next dose as planned.

How to stop using Betnesol-N Drops

Do not stop using Betnesol-N Drops without first talking to your doctor.

If you have been using Betnesol-N Drops for a long period of time (around 6 to 8 weeks), then you should stop using it gradually, to avoid the inflammation coming back. It is important to only use the drops for as long as they are needed.

If you have any further questions about the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines Betnesol-N Drops can cause side effects, although not everybody gets them. These may include:

- Hypersensitivity reactions may occur leading to irritation, itching, redness, burning or a stinging sensation on your skin. These symptoms may not appear until sometime after you have started to use the medicine
- Ulcers on the surface of the eye (cornea). Tell your doctor if your eye becomes painful and if you have blurred vision which does not improve after a few minutes
- Increased pressure in the eye (glaucoma) which can lead to problems with your sight
- A hole in the eyeball (if you have a disease which causes thinning of the surface of the eye)
- Cataracts (clouding of the lens of the eye)
- Enlarged pupils
- Drooping of the eyelid
- Swelling and redness of the outer surface of the eye
- Blurred vision and other alterations to your sight
- 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.
- Microorganisms may become resistant to the anti-biotic if using the drops for a long time.

If you are using Betnesol-N Drops for your nose, you may also experience some of the following side effects:

- If you are a child, Betnesol-N Drops may slow your growth
- Difficulty breathing
- A hole or ulcers on the cartilage wall that separates the nostrils of the nose (nasal septum)
- Irritation and dryness in the nose
- Sneezing
- Headache
- Light-headedness

- Itching
- Feeling sick
- Nosebleeds
- Blocked nose
- Changes in the senses of smell and taste
- Blurred vision.

Using too much of this medicine for a long time could cause side effects in the rest of the body, and stop your adrenal glands making the body's own steroids. This means that when you stop using Betnesol-N Drops, you could experience the following effects:

- Low blood pressure which may make you feel faint
- Fever
- A runny nose
- Painful itchy skin
- Redness of the eye (conjunctivitis)
- Muscle and joint pain
- Weight loss.

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 HPRC Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine

5. How to store Betnesol-N Drops

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

Do not use Betnesol-N Drops after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

The bottle should be disposed of 28 days after first opening, even if there is solution remaining.

Do not store above 25°C. Do not refrigerate or freeze. Keep the bottle in the outer carton to protect it from light.

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 Betnesol-N Drops contains

Betnesol-N Drops contains 0.1% w/v betamethasone sodium phosphate and 3500IU/ml neomycin sulphate.

The other ingredients are Benzalkonium Chloride (anhydrous equivalent), disodium edetate, macrogol 300, sodium formate, anhydrous sodium sulphate, disodium phosphate anhydrous, sodium dihydrogen phosphate dihydrate, sodium hydroxide or phosphoric acid (for pH adjustment) and water for injections.

What Betnesol-N Drops looks like and contents of the pack

Betnesol-N Drops is an eye, ear and nose drops solution. It is colourless to pale yellow liquid.

Betnesol-N Drops comes in 5 ml or 10 ml plastic bottles with a built-in nozzle and a tamper-evident plastic cap.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

RPH Pharmaceuticals AB, Box 603, 101 32 Stockholm, Sweden.

Manufacturer

Excelvision, 27, rue de la Lombardière,
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This leaflet was last updated in 01/2021.

If this leaflet is difficult to see or read or you would like it in a different format, please contact RPH Pharmaceuticals AB, Box 603, 101 32 Stockholm, Sweden.