PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

BETNESOL-N EYE, EAR AND NOSE DROPS

100 mg, 350 mg / 100 ml Solution

Betamethasone sodium phosphate

Neomycin

Read all of this leaflet carefully before you start using BETNESOL-N EYE, EAR AND NOSE DROPS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- BETNESOL-N EYE, EAR AND NOSE DROPS has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What BETNESOL-N EYE, EAR AND NOSE DROPS is and what it is used for
2. What you need to know before you use BETNESOL-N EYE, EAR AND NOSE DROPS
3. How to use BETNESOL-N EYE, EAR AND NOSE DROPS
4. Possible side effects
5. How to store BETNESOL-N EYE, EAR AND NOSE DROPS
6. Contents of the pack and other information

1. What BETNESOL-N EYE, EAR AND NOSE DROPS is and what it is used for

BETNESOL-N EYE, EAR AND NOSE DROPS contains betamethasone sodium phosphate, which is part of a group of medicines called corticosteroids.

BETNESOL-N EYE, EAR AND NOSE DROPS also contains neomycin which prevents the development of bacterial infections.

BETNESOL-N EYE, EAR AND NOSE DROPS is used for treating non infected inflammatory and /or allergic conditions characterised by swelling, itching, redness, pain of the eye, ear and nose.

It is also used where bacterial infection of the ear or nose is present or suspected.

2. What you need to know before you use BETNESOL-N EYE, EAR AND NOSE DROPS

Do not use BETNESOL-N EYE, EAR AND NOSE DROPS:

- If you are hypersensitive (allergic) to betamethasone sodium phosphate, neomycin or any of the other ingredients of BETNESOL-N EYE, EAR AND NOSE DROPS (listed in section 6).
- If you have any kind of fungal, viral, tuberculosis (TB) or discharge producing infection.
- In your eyes if you have a fever blister or cold sore on your eye area.
- In your eyes if your doctor has diagnosed you with glaucoma (an eye disease that causes pain, redness and vison loss due to nerve that provides information to the brain being damaged and/or pressure inside the eye being increased)
- If you have been diagnosed with a hole or tear in your ear drum.
- In your eyes if you wear soft contact lenses
- In new-born children
- If you are pregnant or breastfeeding your baby (see Pregnancy, breastfeeding and fertility).

Warnings and precautions

Special care should be taken with BETNESOL-N EYE, EAR AND NOSE DROPS

- When used in the eye condition commonly referred to as “red eyes”, if the reason for the red eyes has not been confirmed, inappropriate use of BETNESOL-N EYE, EAR AND NOSE DROPS could lead to blindness
- When treatment over prolonged periods is applicable. This should only be done under the strict supervision of your health care provider to avoid complications like the following:

- raised pressure inside the eye that leads to pain, redness and vision loss.
- cataracts (a condition that causes clouding of the lenses and leads to vision problems and vision loss)
- infections that are not immediately noticeable
- sensitivity of the skin to BETNESOL-N EYE, EAR AND NOSE DROPS
- bacteria becoming resistant to the neomycin in BETNESOL-N EYE, EAR AND NOSE DROPS

- If used for longer than 7 days and no improvement is noted as it can cause unexplained worsening of infections due to the infection masking effect of the betamethasone sodium phosphate in the BETNESOL-N EYE, EAR AND NOSE DROPS.
- As the neomycin in BETNESOL-N EYE, EAR AND NOSE DROPS could cause an allergic response when used for a later course of treatment with BETNESOL-N EYE, EAR AND NOSE DROPS or any other neomycin containing product.
- If no improvement is observed within 48 hours (2 (two) days). Speak to your health care provider if this is the case as they may need to refer you to an ophthalmologist (specialist eye doctor) to assure that a sore or fungal infection of the clear layer in the front of the eye or glaucoma (the condition where pain, redness and reduced vision is experiences due to the pressure inside the eye being increased) is not triggered
- If you experience blurred vision or other visual disturbances. This should also be reported to your health care provider for possible referral you to an ophthalmologist to find out the reason for the changes in vision. Which could be due to cataracts or glaucoma (mentioned above) or a rare disease like central serous chorioretinopathy (CSCR) where fluid builds up under the thin layer of tissue that lines the back of the eye.
- If you have been diagnosed with any eye disease that causes thinning of the cornea (the transparent front part of the eye) or sclera (the white part of the eye) as use of BETNESOL-N EYE, EAR AND NOSE DROPS may lead to a further tear or hole in this area.
- When being applied topically to open wounds or damaged skin as the neomycin in BETNESOL-N EYE, EAR AND NOSE DROPS may cause irreversible, partial or total deafness. This effect is especially relevant in the following cases:

- Use of high doses
- Kidney and Liver disease
- Use in infants and small children

- If you’ve been diagnosed with having mitochondrial mutations or if your mother is deaf or has been diagnosed with having a mitochondrial mutation. The neomycin in BETNESOL-N EYE, EAR AND NOSE DROPS, if used in these instances,
  could lead to a condition where hearing or balance problems develop (ototoxicity).
- When being used in the nose soon after nose surgery or if you’ve had an untreated nasal infection or have been diagnosed with pulmonary tuberculosis (TB)

Children and adolescents

- Prolonged treatment in infants should be avoided as it may cause suppression of the adrenal glands which can lead to loss of bodily functions that control food and salt usage which can lead to low blood pressure, weakness, nausea, vomiting and fever
- BETNESOL-N EYE, EAR AND NOSE DROPS should not be used in new-born children as their immature skin and kidneys may cause increased occurrence of side effects.
- BETNESOL-N EYE, EAR AND NOSE DROPS may cause growth retardation in children, even if used at the usual doses.
- When BETNESOL-N EYE, EAR AND NOSE DROPS has been prescribed for prolonged periods for nasal use, the child's height will be carefully monitored by their doctor or health care practitioner and dose adjustments made to the lowest dose at which symptoms can be controlled. They may also be referred to a paediatric specialist.

Other medicines and BETNESOL-N EYE, EAR AND NOSE DROPS

Always tell your health care provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following:

- Medicines such as the antiviral agents cobicistat as they inhibit an important enzyme (CYP3A) which assists in removing toxins or medicines from the body:
  Use of BETNESOL-N EYE, EAR AND NOSE DROPS with these medicines increases the risk of side effects and may require monitoring by your doctor or health care provider.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Corticosteroids such as the betamethasone sodium phosphate included in BETNESOL-N EYE, EAR AND NOSE DROPS has been shown to be cause malformation of the growing foetus in animals following application to the skin and for this reason malformations in humans is also possible.

The neomycin in BETNESOL-N EYE, EAR AND NOSE DROPS may cause hearing or balance problems develop (ototoxicity) in the foetus

You should thus not take BETNESOL-N EYE, EAR AND NOSE DROPS if you are pregnant or breastfeeding your baby.

Fertility: No data is available.

Driving and using machines

BETNESOL-N EYE, EAR AND NOSE DROPS may cause temporary blurring of vision on instillation. You should not drive or operate hazardous machinery unless vision has returned to normal. (see section 4).

It is not always possible to predict to what extent BETNESOL-N EYE, EAR AND NOSE DROPS may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which BETNESOL-N EYE, EAR AND NOSE DROPS affects them (see section 4).

BETNESOL-N EYE, EAR AND NOSE DROPS contains benzalkonium chloride and phosphates

For this reason:

- It should not be used in the eyes if you wear soft contact lenses
- Your doctor or health care practitioner will require that you return to them regularly for examination to ensure that the surface of the clear part of the eye is not adversely affected by the prolonged or repeated use of the benzalkonium chloride preserved BETNESOL-N EYE, EAR AND NOSE DROPS.
- BETNESOL-N EYE, EAR AND NOSE DROPS should be used with caution in the eyes if you are required to take it over a long period of time and you have been advised by your healthcare professional that you have any severe diseases affecting the surface of the eye.
- You may experience eye irritation and other eye related side effects if used in the eye, especially if you are required to use BETNESOL-N EYE, EAR AND NOSE DROPS for a long period of time and also suffer from dry eyes or other diseases of the eye.
- You may experience irritation or swelling in the nose, especially if used for prolonged periods in this area.
- This medicine contains 4,07 mg phosphates in each millilitre of solution which is equivalent to 4.07 mg/ml. 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 BETNESOL-N EYE, EAR AND NOSE DROPS

Do not share medicines prescribed for you with any other person.
Always use BETNESOL-N EYE, EAR AND NOSE DROPS exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose of BETNESOL-N EYE, EAR AND NOSE DROPS is:
EYE: One or two (1 or 2) drops into the eye every one or two (1 or 2) hours until control is achieved, then the frequency may be reduced by your doctor or health care provider.
EAR: Two to three (2 to 3) drops into the ear every two or three (2 or 3) hours until control is achieved, then the frequency may be reduced by your doctor or health care provider.
NOSE: Two or three (2 or 3) drops into each nostril two or three (2 or 3) times daily

Your doctor or health care provider will prescribe the lowest effective dose for the shortest possible time period.

Tell your doctor or health care provider if the eye has not responded within 48 hours, he or she may then refer you to an ophthalmologist.

The same dosage as for adults may be prescribed for use in children, but may be reduced in infants. Use in new-born children however is not recommended.

Due to the growth retardation that is possible in children, the lowest dose that controls symptoms will be prescribed.

Due to the side effects that can occur due to suppression of the adrenal glands in infants, only short term treatment, with the lowest dose, of the least potent medicine that will control the disease will be prescribed.
Your doctor will tell you how long your treatment with BETNESOL-N EYE, EAR AND NOSE DROPS will last. Do not stop treatment early. If you have the impression that the effect of BETNESOL-N EYE, EAR AND NOSE DROPS is too strong or too weak, tell your doctor or pharmacist.

If you use more BETNESOL-N EYE, EAR AND NOSE DROPS than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

The quantity of betamethasone sodium phosphate present in BETNESOL-N EYE, EAR AND NOSE DROPS is such that absorption into the body is unlikely to occur to any significant extent, for this reason overdosage is unlikely. However, appropriate care should be taken as noted under section 2. (What you need to know before you use BETNESOL-N EYE, EAR AND NOSE DROPS) and 4. (Possible side effects)

If you forget to use BETNESOL-N EYE, EAR AND NOSE DROPS

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

BETNESOL-N EYE, EAR AND NOSE DROPS can have side effects.

Not all side effects reported for BETNESOL-N EYE, EAR AND NOSE DROPS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using BETNESOL-N EYE, EAR AND NOSE DROPS, please consult your health care provider for advice.

If any of the following happens, stop using BETNESOL-N EYE, EAR AND NOSE DROPS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Rash or itching that is accompanied by swelling of the hands, feet, face, lips and mouth or throat, which causes difficulty in swallowing or breathing.

These are all very serious side effects. If you have them you may have had a serious reaction to one of the ingredients in BETNESOL-N EYE, EAR AND NOSE DROPS and you will require urgent medical attention or hospitalisation.

Tell your doctor as soon as possible if you notice any of the following

- Blurred vision, vision loss or cloudy patches on the clear layer of the front of the eye
- Painful and redness of eye,
- Increased sensitivity to light
- Excessive tears or discharge
- Ulcers or a tear of the front part of the eye
- Infection, inflammation of the front part of the eye

- Dilated pupils
- Drooping of the upper eyelid
- Partial or total loss of hearing
- Ulceration or a tear of the thin wall dividing your nose into the 2 nasal passages
- Wheezing, dry cough and shortness of breath (bronchial asthma)
  These are all serious side effects that may need referral to a specialist

  Tell your doctor if you notice any of the following:
  Frequent side effects:
- Dryness, irritation of the nose.
  Less frequent side effects
- Hearing or balance problems (ototoxicity).
  Side effects with an unknown frequency
- infection that are not immediately noticeable
- unexplained worsening of infections due to the masking of the infection symptoms by the betamethasone sodium phosphate in BETNESOL-N EYE, EAR AND NOSE DROPS
- Symptoms like weight gain, particularly in the face and the upper back and neck region, facial male-pattern hair growth, increased bruising, stretch marks and acne (collectively these are referred to as cushingoid symptoms).
- Symptoms like tiredness, loss of appetite, stomach pain, joint pain, nausea, vomiting, diarrhoea, irritability and depression, decreased sexual development of the body (collectively, these are all signs of adrenal disease).
- Growth retardation in children and adolescents
- Mental disturbances such as acting different than usual, hyperactivity, sleep problems, anxiety, depression and aggressive, rude and abusive behaviour (these effects are more common in children)
- Irritation of the eyes
- Irritation or swelling inside the nose
- Nausea
- Skin reactions like redness and itchiness
- The development of itchy, round, red welts on the skin. The welts vary in size and appear and fade repeatedly (urticaria).
- Sneezing

- Headache
- Light-headedness
- Nose bleeds
- Worsening of blocked nose
- Smell and taste disturbances.
- Irritation, burning, stinging, itching at the site of administration

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

Reporting can also be done directly to Adcock Ingram Limited at:

E-mail: Adcock.aereports@adcock.com

Tel: 011 635 0134

By reporting side effects, you can help provide more information on the safety of BETNESOL-N EYE, EAR AND NOSE DROPS.

5. How to store BETNESOL-N EYE, EAR AND NOSE DROPS

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light.

Avoid freezing.

Eye drops should be discarded within 28 days of first opening the container.

Do not store in a bathroom.

Do not use after the expiry date stated on the label/carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What BETNESOL-N EYE, EAR AND NOSE DROPS contains

The active substances per 100 ml solution are:

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Betamethasone sodium phosphate 100 mg
Neomycin sulphate equivalent to 350 mg neomycin base
Benzalkonium chloride 0,01 % *m/v* is included as a preservative
The other ingredients are disodium edetate, disodium hydrogen phosphate heptahydrate, phosphoric acid (for pH-adjustment) polyethylene glycol 300, sodium acid phosphate, sodium formate, sodium hydroxide (for pH-adjustment), sodium sulphate anhydrous, water for injection

What BETNESOL-N EYE, EAR AND NOSE DROPS looks like and contents of the pack
BETNESOL-N EYE, EAR AND NOSE DROPS is a clear, colourless to pale yellowish solution.

5 ml or 10 ml solution is packed into an opaque low density polyethylene bottle with an opaque low density polyethylene drop applicator, and sealed with a white polypropylene tamper evident cap. The sealed bottles are packed into unit cartons together with a leaflet

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