SCHEDULING STATUS

S4

BETNESOL EYE, EAR AND NOSE DROPS

1 mg/ml Solution for drops

Betamethasone sodium phosphate

Read all of this leaflet carefully before you start taking BETNESOL 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 healthcare provider.
- BETNESOL 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 EYE, EAR AND NOSE DROPS** is and what it is used for
2. What you need to know before you take **BETNESOL EYE, EAR AND NOSE DROPS**
3. How to use **BETNESOL EYE, EAR AND NOSE DROPS**
4. Possible side effects
5. How to store **BETNESOL EYE, EAR AND NOSE DROPS**

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

- BETNESOL EYE, EAR AND NOSE DROPS contains betamethasone sodium phosphate, which is part of a group of medicines called corticosteroids. These medicines lowers inflammation in the body which eases swelling, itching, redness and allergic reactions. The soluble nature of the betamethasone sodium phosphate has the added

advantage of not containing any particles to cause irritation.

- BETNESOL 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.

2. What you need to know before you take BETNESOL EYE, EAR AND NOSE DROPS

Do not use BETNESOL EYE, EAR AND NOSE DROPS:

- if you are hypersensitive (allergic) to betamethasone sodium phosphate or any of the other ingredients of BETNESOL EYE, EAR AND NOSE DROPS (listed in section 6).
- If you have any kind of bacterial, fungal or viral infection.
- If you have a fever blister or cold sore on your eye area.
- 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 wear soft contact lenses
- if you are pregnant (see Pregnancy, breastfeeding and fertility).
- For prolonged periods in children.
- If you have ulcers, general itchiness or have been diagnosed with a condition called rosacea which is a skin condition that causes red patches and visible blood vessels on the face.
- If you have been diagnosed with a hole or tear in your ear drum.

- In children receiving high doses of betamethasone sodium phosphate or another corticosteroid as it places them at higher risk of diseases such as chickenpox. Note however that vaccination against these organisms should not be done while they are on

treatment as the vaccination might also cause infection.

- If you are struggling with diseases like alcoholism, arthritis or systemic lupus erythematosus. Use of high doses of BETNESOL EYE, EAR AND NOSE DROPS while you have one of these conditions may increase the chances of experiencing bone tissue death that occurs due to a lack of blood supply - this presents as an increased chances of bones fracturing or breaking.
- You have been diagnosed with a disease that causes thinning of the cornea (the transparent front part of the eye) as use of BETNESOL EYE, EAR AND NOSE DROPS may lead to a further tear or hole in the cornea.

Warnings and precautions

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

- As allergic reactions have occurred with the use of BETNESOL 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 EYE, EAR AND NOSE DROPS could lead to blindness
- As it’s use could lead to viral or fungal infections of the cornea (the transparent front part of the eye) as well as other serious complications. For this reason, treatment should not be prolonged, repeated unless this is done under the strict supervision of your medical provider.
- Tell your doctor or medical provider if no response is observed within 48 hours of initiating treatment, or if blurred vision or other visual disturbances are experienced. They will refer you to an ophthalmologist. This is due to the possibility for triggering various eye ailments like glaucoma or fungal infection of the cornea.
- As high doses taken during pregnancy may cause adrenal suppression of the foetus or new-born 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 of the new-born.

If you have been diagnosed with or had any of the following diseases:

- Heart failure (weak heart)
- Heart attack
- High blood pressure
- Diabetes (unusually high blood sugar)
- Seizures (fits)
- Glaucoma
- Hypothyroidism (a condition where the body doesn't create and release enough thyroid hormone into your bloodstream, which makes your metabolism slow down and can make you feel tired, gain weight or unable to tolerate cold temperatures)
- Liver disease/failure
- Osteoporosis (condition where the body's bones weaken and break easily)
- Stomach ulcers
- Mental illness
- Kidney disease

- When being used in elderly patients as they are more likely to suffer from the side effects.
- When being used for prolonged periods. Your medical provider will require that you be examined more regularly in this instance.

- As cataracts (a condition that causes clouding of the lenses and leads to vision problems and vision loss) has been reported to have developed after prolonged treatment of eye conditions with BETNESOL EYE, EAR AND NOSE DROPS

- Your doctor or healthcare provider will prescribe the lowest effective dose for the shortest possible time period. If your doctor or medical provider has prescribed BETNESOL EYE, EAR AND NOSE DROPS at a high dose and for use over a prolonged period, it may bring about:

- 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 a disease state called adrenal suppression).
- Growth retardation in children and teenagers
- Clouding of the coloured part of the eye that can lead to vision problems/ loss (cataracts) or additional pain, redness due to the pressure inside the eye being increased (glaucoma).
- Hyperactivity, sleep disorders, anxiety, depression or aggression – though this occurs more often in children, it also occurs very rarely.
- A decreased ability of the body to fight infections, this is more common if you are taking medicines to treat cancer or have an already weakened system.
- Death of bone tissue due to a lack of blood supply This is more common if you have been prescribed BETNESOL EYE, EAR AND NOSE DROPS for use at a high dose and are also suffering from diseases like alcoholism, arthritis or systemic lupus erythematosus.

Children and adolescents

- Children may be at increased risk of some side effects of BETNESOL EYE, EAR AND NOSE DROPS
- BETNESOL EYE, EAR AND NOSE DROPS may cause growth retardation in children, even if used in small doses.
- When BETNESOL EYE, EAR AND NOSE DROPS has been prescribed for prolonged periods, their height will be carefully monitored by their doctor or health care practitioner and dose adjustments may be made or they may be referred to a paediatric specialist.

- Children receiving high doses of BETNESOL EYE, EAR AND NOSE DROPS are at special risk of diseases, such as chickenpox, but should not be vaccinated with these organisms while on treatment since it may cause them to become infected with them.

Other medicines and BETNESOL EYE, EAR AND NOSE DROPS

Always tell your healthcare 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 following as they inhibit an important enzyme (CYP3A) which assists in removing toxins or medicines from the body:
    - Birth control medicines
    - Antiviral agents like ritonavir and cobicistat,

Use of BETNESOL EYE, EAR AND NOSE DROPS with these medicines increases the risk of side effects and may require monitoring by your doctor or healthcare provider.

- Medicines containing any of the following as they tend to reduce the effect of BETNESOL EYE, EAR AND NOSE DROPS:
    - Phenobarbitone and other medicines in this class.
    - Carbamazepine, phenytoin, primidone, or rifampicin.
- Medicines containing any of the following as they cause low potassium levels in the body and may lead to muscle cramps, feeling tired, weakness, and constipation
    - Hydrochlorothiazide and other medicines like it
    - Furosemide
    - Amphotericin B
    - Theophylline, salbutamol and other medicines like them that ease breathing by opening up the airways to the lungs.

- Medicines such as aspirin or ibuprofen as taking them together with BETNESOL EYE, EAR AND NOSE DROPS increases the chances of developing ulcers and bleeding in the stomach
- Anticoagulant medicines, as your body may respond differently to them.
- Salicylates (like aspirin) and medicines used for diabetes or high blood pressure, as your doctor or healthcare provider may need to increase your dosage of these medicines.
- Antimuscarinic medicines like when they are being used for the eye condition called myasthenia gravis
- Medicines that are used for their muscle relaxation effect
- Immunosuppressive or cytotoxic medicines such as those used for the treatment of cancer, lupus, rheumatoid arthritis or to prevent rejection of transplanted organs.

Pregnancy, breastfeeding and fertility

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

High doses taken during pregnancy may cause adrenal suppression of the foetus or new-born 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 of the new-born.

Corticosteroids such as the active ingredient included in BETNESOL EYE, EAR AND NOSE DROPS have 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.

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 healthcare provider for advice before taking this medicine.

Driving and using machines

BETNESOL EYE, EAR AND NOSE DROPS may cause temporary blurring of vision on instillation. You should be thus not to 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 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 EYE, EAR AND NOSE DROPS affects them (see section 4).

BETNESOL EYE, EAR AND NOSE DROPS contains benzalkonium chloride

For this reason:

- It should not be used in the eyes if you wear soft contact lenses
- It should not be used in the eyes if you have redness, itching, swelling, pain or infection on the eyelids, the tissue around the eye or on the surface of the eye.
- You may experience eye irritation and other eye related side effects if used in this area and you also suffer from dry eyes or other diseases of the eye.
- Your doctor or health care practitioner will require that you return to them regularly for examination

You may experience irritation or swelling in the nose, especially if used for prolonged periods in this area.

3. How to take BETNESOL EYE, EAR AND NOSE DROPS

Do not share medicines prescribed for you with any other person.

Always take BETNESOL 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 EYE, EAR AND NOSE DROPS is:

EYE: One or two drops into the eye every one or two hours until control is achieved, when the frequency may be reduced by your doctor or healthcare provider.
EAR: Two to three drops into the ear every two or three hours until control is achieved, when the frequency may be reduced by your doctor or healthcare provider.
NOSE: Two or three drops into each nostril two or three times daily

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

Your doctor will tell you how long your treatment with BETNESOL EYE, EAR AND NOSE DROPS will last. Do not stop treatment early. If you have the impression that the effect of BETNESOL EYE, EAR AND NOSE DROPS is too strong or too weak, tell your doctor or pharmacist.

If you take more BETNESOL 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 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 EYE, EAR AND NOSE DROPS) and 4. (Possible side effects)

If you forget to take BETNESOL EYE, EAR AND NOSE DROPS

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

If you stop taking BETNESOL EYE, EAR AND NOSE DROPS

It may lead to:

- Constant tiredness, muscle weakness, loss of appetite, weight loss, stomach pain, nausea, vomiting, diarrhoea, low blood pressure that drops further when you stand up,

causing dizziness or fainting, irritability and depression, joint pain, craving salty foods, low blood glucose, irregular or no menstrual periods and loss of interest in sex. This condition may also be triggered if your body gets an infection or undergoes any form of trauma like an accident or surgery at the same time of your withdrawal. A sudden dose reduction could have the same triggering effect and symptoms may be experienced for months or years.

- Fever, muscle pain, point pain, weight loss, headache, vomiting.

If used for more prolonged treatment periods (over 6 to 8 weeks), your health care provider will withdraw your use of BETNESOL EYE, EAR AND NOSE DROPS slowly to avoid relapse. If it was taken for just a short period, gradual stopping of it's use will not be necessary.

4. Possible side effects

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

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

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

- Increased clotting of the blood. Depending on where the clot ends up it may affect the lungs (characterised by symptoms like shortness of breath, chest pain, coughing up blood), legs or arms (characterised by symptoms like swelling, pain, warmth, coldness, numbness, darkened skin), brain (characterised by symptoms like headaches, limb weakness, difficulty speaking). This effect may lead to organ failure and death due to lack of supply to the organ in question.

Tell your doctor if you notice any of the following:

Frequent side effects:

- A mild rise in ocular tension (will be diagnosed by your doctor or healthcare provider)
- Increased appetite

Less frequent side effects

- A serious rise in ocular tension (will be diagnosed by your doctor or healthcare provider)
- Ulceration or a tear of the thin wall dividing your nose into the 2 nasal passages.

Side effects with an unknown frequency

- Delayed wound healing
- Increased likelihood, spread and severity of infections
- Masking of infections
- 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).
- 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).
- Growth retardation
- Low potassium levels in the body which is characterised by muscle cramps, feeling tired, weakness, and constipation
- Loss of bone mass with subsequent tendency towards fractured and bones breaking.
- Decreased nitrogen in the body that can lead to a reduced ability of the body to make/replace hair, bodily tissues and muscles.
- High blood sugar, characterised by increased thirst, dry mouth, needing to pee frequently, tiredness, blurred vision, unintentional weight loss, recurrent infections
- Mental disturbances such as acting different than usual, withdrawn and depressed, anxiety, aggressive, rude and abusive or a change in habits.

- Neurological disturbances such as paralysis, muscle weakness, poor coordination, loss of sensation, seizures, confusion, pain and altered levels of consciousness.
- Cataracts - a condition that causes clouding of the lenses of the eyes and leads to vision problems and vision loss
- Ulcers of the eye
- Fungal infection, inflammation (keratitis)or calcification of the transparent front part of the eye, characterised by blurred vision painful and redness of eye, increased sensitivity to light, and excessive tears or discharge.
- Glaucoma, which is 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.
- Reduced or blurred vision
- Dilated pupils
- Drooping of the upper eyelid
- Heart failure which is characterised by symptoms such as shortness of breath with activity or when lying down, tiredness and weakness, swelling in the legs, ankles and fee or rapid or irregular heartbeat
- Swelling
- High blood pressure which will be diagnosed by your doctor as it may not have any symptoms or may cause headaches, shortness of breath or nosebleeds.
- Bronchial asthma which may be characterised by shortness of breath.
- Acute pancreatitis which is characterised by pain in the abdominal area that radiates to the back, nausea and vomiting, fever and chills, a tender and swollen abdomen, diarrhoea, fat in the stool and indigestion
- Nausea
- Loss elasticity, thinning or the development of round, red welts together with itching of the skin.

- Death of bone tissue due to a lack of blood supply which can lead to fractures and breaks of the bones
- Muscle wasting with resultant impaired ability to perform physical activities
- Menstrual irregularities
- Dryness, irritation of the thin wall dividing your nose into the 2 nasal passages.
- Nose bleeds
- Smell and taste disturbances.
- Sneezing
- Headache
- Light-headedness
- Worsening of nasal congestion
- 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 EYE, EAR AND NOSE DROPS.

5. How to store BETNESOL 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 four weeks of first opening the container.
- Keep in the original packaging until required for use.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label.
- 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 EYE, EAR AND NOSE DROPS contains

The active substance is 1mg betamethasone sodium phosphate in 1ml sterile stabilised solution

The other ingredients are benzalkonium chloride, disodium edetate, sodium chloride and water for injection.

What BETNESOL EYE, EAR AND NOSE DROPS looks like and contents of the pack

BETNESOL EYE, EAR AND NOSE DROPS is a colourless to slightly yellow, clear solution, free from particles.

5 ml 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

Holder of Certificate of Registration

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