

PATIENT INFORMATION LEAFLET

X BETA N EYE, EAR & NASAL DROPS, Betamethasone Sodium Phosphate 0.1%w/v & Neomycin Sulphate 0.5% w/v

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, health care provider 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 you get any side effects or if any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

What is in this leaflet:

- a) What X BETA N DROPS is and what it is used for
- b) Before you use X BETA N DROPS
- c) How to use X BETA N DROPS
- d) Possible side effects
- e) How to store X BETA N DROPS
- f) Further information

a) What X BETA N DROPS is and what it is used for

X BETA N DROPS belongs to a group of medicines called topical corticosteroids. The drops work by reducing inflammation (redness, itching and soreness). The drops also contain neomycin sulphate which prevents bacterial infection. X Beta N drops are used to treat inflammation of the eye, ear or nose when there may be a risk of bacterial infection.

Before you use X BETA N DROPS

DO NOT use X BETA N DROPS:

- In your eyes without first checking with your doctor, If used for the wrong condition, it could lead to blindness.
- If you have an infection in the eye, or the eye is producing pus and is sticky
- If you have an infection in the ear or nose
- If you have ulcers in your eyes (shingles)
- If you have glaucoma (increased pressure in the eye)

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- You have a perforated ear drum.
- If you are allergic to any of the other ingredients of this medicine.
- If you are wearing contact lenses.

Take special care

Talk to your doctor or nurse, health care provider before using X BETA N DROPS if:

- You experience an allergic reaction to X BETA N DROPS.
- 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 have been treated with X Beta N drops or similar corticosteroid medicine recently. You should not use corticosteroids for a long time without regular medical checkups 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 eye ball.
- 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 you wear contact lenses – stop wearing your lenses if you have any signs or symptoms of an eye infection. Wear your glasses instead. Do not start wearing your lenses again until the signs and symptoms of the infection have cleared and until you have stopped using the medicine.
- This medicine contains a certain level of 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.

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Other medicines and X BETA N DROPS

Tell your doctor or nurse if you are taking or have recently taken, or might take any other medicines, including medicines obtained without a prescription.

Some medicines may increase the effects of x Beta 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, or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking any medicine.

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.

Effects on ability to drive and use machines

X BETA N DROPS may cause temporary blurred vision on instillation. Do not drive or use machinery until your vision has cleared.

b) How to use X BETA N DROPS

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

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

Things to remember about your dose: • Always use X Beta N exactly as your doctor has told you • 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. If there is no improvement in your symptoms after 7 days, stop using the drops and see your doctor again.

If you are using in combination with another eye drop medicine, wait 5-15 minutes before applying the second eye drops.

Instructions for use

You must not use the bottle if the tamper-proof seal on the bottle neck is broken before you first use it. First wash your hands.

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Using the drops for the first time:

These drops come in a bottle with a coned shaped nozzle and screw cap. The inside of the screw cap contains a spike. The screw cap is fitted to the bottle in such a way that there is no contact between the spike and the top of the nozzle of the bottle. In order to open the bottle, it is necessary to tighten the screw cap further, so that the edge of the screw cap and the nozzle edge are totally aligned. At this point the screw cap spike will pierce the top of the nozzle of the bottle, which will open the bottle. Once the bottle has been opened in this way, unscrew the screw cap fully to remove it from the bottle and apply the eye drops.

Recommended doses

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.

Tilt the head back. Gently pull lower eyelid downwards and outwards. Place drops in the gap between the lid and eye (squeeze bottle very gently if necessary). Blink a few times to spread out the drops. Repeat for the other eye if needed.

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.

Tilt the head to one side. Place drops in the ear canal (squeeze bottle gently if necessary). Keep head tilted for a minute or two to let the drops soak in. Repeat for the other ear if needed.

Nose

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

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

To avoid contamination, do not touch or allow the dropper tip touch the eye, ear or nose. It may become contaminated with bacteria.

If you receive more X BETA N DROPS than you should

In the event of acute over dosage X BETA N DROPS is unlikely to lead to any serious side effects however, if concerned, contact the nearest hospital near you.

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If you forget to use X Beta N drops

Apply the drops as soon as you remember. However, if it is almost time for your next dose, do not take a double dose to make up for a forgotten dose.

How to stop using X Beta N drops

c) Possible side effects

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

These may include:

- 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.
- Itchy, red or irritated skin. This may not appear until sometime after you have started to use the medicine
- A burning or stinging sensation on your skin. This may not appear until sometime after you have started to use the medicine
- Bugs may become resistant to the anti-biotic if using the drops for a long time.
- If you are using X Beta N Drops for your nose, you may also experience some of the following side effects:
 - If you are a child, X Beta N Drops may slow your growth
 - Difficulty breathing
 - A hole or ulcers of the tissue that divides the nose (nasal septum)

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- Irritation and dryness in the nose • Sneezing • Headache • Lightheadedness • Itching • Feeling sick • Nosebleeds • Blocked nose • Changes in your senses of smell and taste.
- Using too much of this medicine for a long time can prevent your adrenal gland from working properly and producing your body's own natural steroids (known as adrenal suppression). This means that when you stop using X Beta 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.

d) How to store X BETA N DROPS

Use as directed by physician. Keep out of reach of children.

Do not store above 30°C and protect from excessive heat and freezing

Do not use after the expiry date which is stated on the bottle after "Expiry". The expiry date refers to the last day of that month.

Throw the bottle away 28 days after opening, even if there is solution remaining.

Do not use X BETA N DROPS if you notice the tamper-proof seal is broken.

Do not throw away any medicines via waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

e) Further information

What X BETA N DROPS contains

The active substance is betamethasone sodium phosphate at a concentration of 0.1% w/v and neomycin sulphate at a concentration on 0.5% w/v.

The other Ingredients are Sodium chloride, Thiomersal, disodium edetate and water for injection.

What X BETA N DROPS looks like and the contents of the pack

X BETA N DROPS is a clear colorless to pale yellow solution practically free from particles supplied in either a 5 ml or 10 ml in low density polyethylene (LDPE) container enclosed in a mono carton with a leaflet.

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This leaflet was last revised in APRIL 2023.