



**Please read this leaflet carefully before you start use X-SONE N Eye/Ear drops U.S.P.**



**X-SONE-N**  
Eye- Ear drops

**Composition**

Dexamethasone Sodium Phosphate U.S.P.  
equivalent to Dexamethasone Phosphate..... 0.1%w/v  
Neomycin sulphate U.S.P  
equivalent to neomycin base.....0.35%w/v  
Benzalkonium chloride B.P as preservative.....0.01%w/v  
Sterile Aqueous vehicle.....q.s

**Pharmacological properties**

Dexamethasone is a potent synthetic glucocorticoid with little, if any, mineralocorticoid activity, and has a long duration of action. It suppresses inflammatory cell influx and inflammatory process.  
Neomycin "irreversibly" binds to specific 30S-subunit proteins and 16S rRNA. Specifically Neomycin binds to four nucleotides of 16S rRNA and a single amino acid of protein S12. This interferes with decoding site in the vicinity of nucleotide 1400 in 16S rRNA of 30S sub-unit. This region interacts with the wobble base in the anticodon of tRNA. This leads to interference with the initiation complex, misreading of mRNA so incorrect amino acids are inserted into the polypeptide leading to nonfunctional or toxic peptides and thus prevents or interferes with the protein synthesis in the bacteria

**Indications**

**Eye,** treatment of inflammatory conditions of the anterior segment of the eye complicated by infection caused by organism sensitive to neomycin.  
**Ear,** treatment of inflammatory conditions of the external ear complicated by infection caused by organism sensitive to neomycin.

**Dosage**

Eye: 1-2 drops every 1-2 hrs or as prescribed by the physician  
Ear: 2-3 drops every 2-3 hrs or as prescribed by the physician

**Contraindications**

This drug should not be used in presence of acute herpes simplex, tuberculosis of the eye, fungal diseases of ocular or auricular structures, vaccinia, varicella and most viral diseases of the cornea and conjunctiva. It is contraindicated in perforated drum membrane, and in patients sensitive to any of its components.

**Precautions**

Prolonged use may result in glaucoma, damage of the optic nerve, defects in visual acuity and fields of vision, posterior sub-capsular cataract formation or may aid in establishment of secondary infections. If this product is used for 10 days or longer, intraocular pressure should be routinely monitored.  
In those diseases causing thinning of the cornea, perforation has been known to have occurred with use of topical steroids. As with other antibiotic containing preparations, prolonged use may result in overgrowth of non-susceptible organisms. Caution is also required in pregnancy or if you are breast feeding a baby.  
Do not wear soft contact lenses whilst using X-SONE-N as the preservative may damage the lens.

**Drug interactions**

X-SONE-N applied topically is not likely to produce significant drug interactions. Systemically, neomycin may enhance the anticoagulant effects of warfarin. Its ototoxicity may be increased by ethacrynic acid and furosemide.  
Concurrent use of barbiturates, phenytoin, or rifampicin may enhance the metabolism and decrease the effect of corticosteroids.

**Side effects**

Burning sensation, discomfort and itching. Elevation of intra ocular pressure and possible development of glaucoma.

**Presentation**

Clear, colorless or faintly yellow solution in sterile plastic dropper bottles of 10ml and 5ml enclosed in protective carton with leaflet.

**Shelf life**

The manufacturing and expiry dates are indicated on the packing.

**Storage**

Store below 30° C but do not freeze, protect from light.  
Discard after the expiration date or 4 weeks after opening the bottle.

KEEP OUT OF REACH OF CHILDREN.

**Direction for use**

Tighten the cap on the nozzle  
The spike in the cap will pierce the tip of the vial.  
Dispense drops with gentle pressure.  
Replace the cap after every use.



**Warning**

1. If irritation persists or increases, discontinue the use and consult a physician.
2. Do not touch the vial tip or other dispensing tip to any surface since this may contaminate the solution.
3. Use the solution within four weeks after opening the vial.



**Wash your hands well before use.**

**For the Eye Drops:**

1. Remove the outer cap.
2. Tilt the head back and pull the lower lid of the eye down to form a pocket.
3. Hold the container between the thumb and middle finger of the other hand, turn the container upside down near to the eye, and try not to touch the eye.
4. Apply enough pressure to the container to release one to two drops
5. Close the eye and keep it closed for one to two minutes
6. If you think you have missed the eye, then insert another drop.
7. Repeat in the other eye if you have been instructed to use this preparation in both eyes.
8. Replace the outer cap on the container, try not to touch the applicator tip with the fingers as you do so.
9. Wash your hands

**For the Ear Drops:**

1. Clean the ear with warm water and dry thoroughly
2. Remove the outer cap
3. Lie down or tilt the head so that the affected ear is facing upwards.
4. Gently pull the ear lobe to straighten the ear canal
5. Hold the container between the thumb and middle finger of the other hand, turn the container upside down near to the ear, try not to touch the inside of the ear.
6. Apply enough pressure to the container to release three to four drops of **X-SONE-N**.
7. Keep the ear facing up for a few minutes to allow the solution to come into contact with the affected area
8. Repeat in the other ear if you have been instructed to use **X-SONE-N** drops in both ears
- 9 . Replace the outer cap on the container
10. Wash your hands

For further information, please consult your pharmacist or physician

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Manufactured by:  
**Abacus Parenteral Drugs Ltd.**  
Factory: Block 191, Plot No. 114, Kinga, Mukono,  
Head Office: P.O. Box. 31376 Kampala, Uganda.  
Tel: +256 312 380800, Fax: +256 312 380820,  
E-mail: apdl@abacuspharma.com  
website: www.abacusparenteral.com

Department	Name	Sign	Date
FND			
Q.C			
Q.A			
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