

FRONT

Betasol-N

(Betamethasone Sodium Phosphate B.P. with Neomycin Sulphate B.P. Eye/Ear/Nasal Drops)

Composition:

Betamethasone Sodium Phosphate B.P 0.1% w/v
and Neomycin Sulphate B.P 0.5% w/v

Preservatives:

Phenyl Ethanol U.S.P 0.25 %
Thiomersal B.P 0.005%

Indications:

Eye: Non-Infected steroid responsive Inflammatory Conditions e.g. Uveitis., Marginal keratitis, Allergic conjunctivitis, Blepharitis, Episcleritis. Where prophylaxis against secondary bacterial infection is desired.

Ear: Otitis externa and other steroid responsive inflammatory conditions where bacterial infection is present or suspected.

Nose: Steroid responsive inflammatory conditions where infection is present or suspected.

Dosage and Administration:

Eye: 1 or 2 drops instilled into the eye every one or two hours until signs of improvement are apparent, then the frequency may be reduced.

Ear: 2 or 3 drops instilled into the ear every two or three hours until signs of improvement are apparent, then the frequency can be reduced.

Nose: 2 or 3 drops instilled into each nostril two or three times daily.

Contraindications:

Bacterial, viral, fungal tuberculous or purulent conditions. Use in the eye is contraindicated if glaucoma is present or where herpetic keratitis (e.g. dendritic ulcer) is considered a possibility. Inadvertent use of topical steroids in the latter condition can lead to extension of the ulcer and marked visual deterioration.

Hypersensitivity to the preparation: Because of the risk of ototoxicity, preparation containing neomycin should not be used until an intact tympanic membrane has been visualized.

Precautions:

Steroids should not be administered to 'red' eyes until a definitive diagnosis is made. Treatment with steroid preparations should not be repeated or prolonged without regular review to exclude raised intra-ocular pressure or unsuspected infections. The unnecessary topical use of neomycin containing products should be avoided in order to minimize occurrence of neomycin resistant organisms (and organisms cross-resistant to other amino glycosides). Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development. The relevance of

BACK

this finding to human beings has not been established; however topical steroids should not be used extensively in pregnancy, i.e. in large amounts or for prolonged periods.

Side Effects:

Eye drops containing corticosteroids cause a serious rise in intra-ocular pressure in a small percentage of the population, including most of those with a family history of glaucoma. A milder rise may be experienced by a larger proportion of subjects if treatment is continued for longer than a few weeks. Thinning of the cornea leading to perforation has occurred with use of topical corticosteroids. Acute sensitization to neomycin is a rare event. Cataract is reported to have occurred after unduly prolonged treatment of eye conditions with topical corticosteroids. Excessive and prolonged intranasal usage above the recommended dose may induce systemic side-effects.

Pharmaceutical Precautions:

Betasol -N contents should not be used more than four weeks after first opening the bottle.

Storage conditions:

The solution turns yellow on storage. This does not affect efficacy of the product. Store in a dry and dark place preferably at a temperature below 30°C. Keep out of the reach of children. Bottle must be stored upright.

Presentation:

7.5 ml sterile solution available in plastic dropper bottle.



Manufactured by:

MBL Pharma

B-77-A, H.I.T.E.,
LASBELA, PAKISTAN.
www.mblgroup.net