ANTILERG-F

Dexamethasone Phosphate + Neomycin (0.1+0.35)%
Eye drops

1. Product Name: ANTILERG-F

2. Composition: Active ingredients:

Dexamethasone Sodium Phosphate	1.098mg/ml
equivelant to Dexamethasone Phosphate	1.000mg/ml
Neomycin Sulphate	5.000mg/ml
equivelant to Neomycin base	3.500mg/ml

3. Product Description: Antilerg F is a clear, colourless to pale yellow solution.

4. Pharmacodynamic Properties: Dexamethasone is a corticosteroid, which suppresses the inflammatory response to a variety of agents and probably delays or slows healing.

Since corticosteroids may inhibit the body's defence mechanism against infection, a concomitant antimicrobial drug may be used.

Neomycin sulphate, the anti-infective component of ANTILERG-F, is included to provide action against specific microorganism susceptible to it. Neomycin Sulphate, the particular anti-infective drug in ANTILERG-F, is active against the following common bacterial eye pathogens: *Staphylococcus aureus*, *Escherichia coli*, *Haemophilus influenzae*, *Klebsiella/Enterobacter* species, *Neisseria* species. ANTILERG-F does not provide adequate coverage against *Pseudomonas aeruginosa*, *Serratia marcenes* and Streptococci, including *Streptococcus pneumonicae*.

When a decision to administer both a corticosteroid and an antimicrobial is made, the administration of such drugs in combination has the advantage of greater patient compliance and convenience, with the added assurance that the appropriate dosage of both drugs is administered, plus assured compatibility of ingredients when both types of drug are in the same formulation and particularly that the correct volume of drug is delivered and retained.

The relative potency of corticosteroids depends on the molecular structure, concentration and release from the vehicle.

Pharmacokinetic Properties: a. General Characteristics**:** Dexamethasone is absorbed during topical use, but its absorption is important only in high doses and prolonged use. Neomycin can be absorbed during topical use only if there is damage at the tissues. b. Characteristics in patients: No important pharmacokinetic reactions are observed during administration of ANTILERG-F in patients.

5. Indications: ANTILERG-F is indicated for steroid-responsible inflammatory ocular conditions, for which a corticosteroid is indicated and where bacterial infection or risk of bacterial ocular infections exists.

Ocular steroids are indicated in inflammatory conditions of the palpebral and bulbar conjuctiva, cornea and anterior segment of the globe where the inherent risk of steroid use in certain infective conjuctivitides is accepted to obtain a diminution in edema and inflammation. They are also indicated in chronic anterior uveitis and corneal injury from chemical, radiation or thermal burns, or penetration of foreign bodies.

The use of a combination drug with an anti-infective component is indicated where the risk of infection is high or where there is an expectation that potentially dangerous numbers of bacteria will be present in the eye.

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6. Dosage and administration: Instill 1 or 2 drops into the conjunctival sac every hour during the day and every 2 hours during the night as initial therapy. When a favourable response is observed, reduce dosage to 1 drop every 4 hours. Later, further reduction in dosage to 1 drop 3 or 4 times daily may suffice to control symptoms.

Not more than 20 ml should be prescribed initially and the prescription should not be refilled without further evaluation.

7. Contraindications: ANTILERG-F is contraindicated in most viral diseases of the cornea and conjunctiva, including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicelia and also in mycobacteria infection of the eye and fungal diseases of ocular structures. It is also contraindicated in people with known or suspected hypersensitivity to any of the components of the drug and to other corticosteroids.

8. Warnings and precautions: The initial prescription and renewal of the medication order beyond 20 ml should be made by a physician only after examination of the patient with the aid of magnification, such as slit-lamp biomicroscopy and, where appropriate, fluorescein staining.
The possibility of persistent fungal infections of the cornea should be considered after prolonged corticosteroid dosing. Prolonged use may result in ocular hypertension and/or glaucoma, with damage to the optic nerve, defects in visual acuity and fields of vision and posterior subcapsular cataract formation.
Prolonged use may suppress the host response and thus increase the hazard of secondary ocular infections. In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical corticosteroids. In acute purulent conditions of the eye, corticosteroids may mask infection or enhance existing infection. If this product is used for 10 days or longer, intraocular pressure should be routinely monitored even though it may be difficult in children and uncooperative patients. Corticosteroids should be used with caution in the presence of ocular hypertension and/or glaucoma. Intraocular pressure should be checked frequently. The use of corticosteroids after cataract surgery may delay healing and increase the incidence of filtering blebs. Employment of corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution: periodic slit-lamp microscopy is recommended. Neomycin sulphate may occasionally cause cutaneous sensitization. If any reaction indicating such sensitivity is observed the use of the drug should be discontinued. Avoid allowing the tip of the flacon to contact the eye, eyelid, fingers or any other surface. The use of this product by more than one person may spread infection. Keep tightly closed when not in use. Ocular preparations handled improperly, can become contaminated by common bacteria, known to cause ocular infections. Serious damage to the eye and subsequent loss of vision may result by using contaminated preparations. If redness, irritation, swelling or pain persists or becomes aggravated you should consult your physician. If you have ocular surgery or develop an intercurrent ocular condition (e.g. trauma or infection) you should immediately seek for your physician's advice.
Excipients: Benzalkonium Bromide is used as an antimicrobial preservative for pharmaceutical products.
9. Interaction with other medicinal products and other forms of interaction: None stated.
10. Statement and usage during pregnancy and lactation:
Pregnancy: There are no adequate studies in pregnant women. The drug should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
Lactation: It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Special care should be taken for the use of corticosteroids during lactation.
11. Adverse Effects/Undesirable Effects:
Reactions occurring most often from the presence of the anti-infective ingredient are allergic sensitization. The reactions due to the corticosteroid component are: elevation of intraocular pressure with possible development of glaucoma and infrequent optic nerve damage, posterior subcapsular cataract formation and delayed wound healing. The development of secondary infection has occurred after use of combinations containing corticosteroids and antimicrobials. Fungal and viral infections of the cornea are particularly prone to develop coincidentally with long-term applications of corticosteroids. The possibility of fungal invasion must be considered in any persistent corneal ulceration where corticosteroid treatment has been used. Secondary bacterial ocular infection following suppression of host responses also occurs.
12. Overdose and Treatment: Not applicable as Antilerg-F is not absorbed into the systemic circulation
13. Storage Conditions: Store below 30 ^{o}C, protected from light. Keep out of the sight and reach of children.
14. Dosage Forms and packaging available: The product is packed in polyethylene vials, containing 8 ml, and in a carton box of 24 vials.
15. Name and Address of the Manufacturer: DEMO S.A PHARMACEUTICAL INDUSTRY, 21st km National Road Athens-Lamia, 145 68 Krioneri, Attiki, Greece. Tel: +30 210 8161802, Fax: +30 210 8161587.
16. Name and Address of the Product Registration Holder:
Pahang Pharmacy Sdn. Bhd.,
Lot 5979, Jalan Teratai,
5 1/2 Mile Off Jalan Meru,
41050 Klang, Selangor, Malaysia
17. Date of Revision of Package Insert: April 2020.

Reg. No.: MAL19950530AZ

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