Dexamethasone Sodium Phosphate Ophthalmic Solution USP,
0.1% Dexamethasone Phosphate Equivalent (Sterile)

Rx only

**FOR USE IN THE EYES OR EARS**

**DESCRIPTION**

Dexamethasone Sodium Phosphate Ophthalmic Solution USP is a sterile, topical steroid solution. The active ingredient is represented by the following structural formula:

![Chemical Structure](image)

**Chemical Name**: 9-fluoro-11β,17-dihydroxy-16α,17α-didehydrocortico-11β-ol (9α-fluoro-11β,17α-dihydrocortico-11β-ol)

**Molecular Formula**: C_{22}H_{28}FNa_{2}O_{8}P

**Mol. wt.**: 516.41

**Active**: Dexamethasone Sodium Phosphate, equivalent to 1 mg (0.1%) Dexamethasone Phosphate. **Inactive**: Sodium Citrate, Sodium Borate, Creatinine, Polysorbate 80, Edetate Disodium Dihydrate, Purified Water. Hydrochloric Acid may be added for 10 days or longer, intraocular pressure should be routinely monitored even though it may be difficult in children and uncooperative patients.

**INDICATIONS AND USAGE**

For the treatment of the following conditions:

- **Ophthalmic**: Sterile, anti-inflammatory condition of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe, such as allergic conjunctivitis, acne rosacea, superficial punctate keratitis, herpes zoster ophthalmicus, iritis, vernal, and xerotic conjunctivitis.

- **Topical**: Ocular: Steroid responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe, such as allergic conjunctivitis, acne rosacea, superficial punctate keratitis, herpes zoster ophthalmicus, iritis, vernal, and xerotic conjunctivitis.

**CONTRAINDICATIONS**

- Ophthalmic: Systemic or ocular fungal or herpetic infections, previous occurrence of fungal ocular infection.

**WARNINGS**

- Hypersensitivity to any component of this product, including sulfites (see PRECAUTIONS).
- Patients should be instructed to avoid allowing the tip of the dispensing container to contact the eye or surrounding structures.
- Steroid responsive inflammatory conditions of the external ocular surface, such as allergic conjunctivitis, keratoconjunctivitis sicca, and vernal conjunctivitis when the inherent hazard of steroid use is accepted to obtain an advisable diminution in edema and inflammation.

**PRECAUTIONS**

- Steroid responsive inflammatory conditions of the eyes and eyelids should be considered after prolonged corticosteroid dosing.

- There are no adequate and well-controlled studies in pregnant women. Dexamethasone sodium phosphate ophthalmic solution should be used during pregnancy only if the potential benefit to the mother justifies the potential risk to the embryo or fetus. Infants born to mothers who have received substantial doses of corticosteroids during pregnancy should be observed carefully for signs of hypoadrenalism.

**ADVERSE REACTIONS**

- Systemic overuse may result in suppression of hypothalamic-pituitary-adrenal (HPA) axis, which can lead to adrenal insufficiency. In these cases, the sudden withdrawal of corticosteroid therapy may precipitate an acute exacerbation of such conditions. If necessary, gradually decrease the dose over several months in order to minimize withdrawal of the adverse effects. (See PRECAUTIONS, General.)

- In acute purulent conditions of the eye or ear, corticosteroids may mask infection or enhance existing infection. If these products are used for 10 days or longer, infection may develop or worsen. Topical corticosteroids may result in the development of persistent fungal infections of the cornea. This product contains sulfites, which may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in nonasthmatic people.

**ADDITIONAL INFORMATION**

- Steroids may suppress the normal adaptive immune response. Patients should be instructed to avoid allowing the tip of the dispensing container to contact the eye or surrounding structures.

**INFORMATION FOR PATIENTS**

- Patients should be instructed to avoid allowing the tip of the dispensing container to contact the eye or surrounding structures.

**PATIENTS WITH ASTHMA**

- Patients should be instructed to avoid using the product in the eyes.

**PREGNANCY**

- Pregnancy Category C: Dexamethasone has been shown to be teratogenic in mice and rabbits following topical ocular administration in mid-late gestation. It is also teratogenic in rabbits at 15 times the therapeutic dose in pregnant rabbits. There are no adequate and well-controlled studies in pregnant women. Dexamethasone sodium phosphate ophthalmic solution should be used during pregnancy only if the potential benefit to the mother justifies the potential risk to the embryo or fetus.

**LACTATING WOMEN**

- Dexamethasone sodium phosphate ophthalmic solution is contraindicated in lactating women. In case of exposure, patients should be instructed to avoid allowing the tip of the dispensing container to contact the eye or surrounding structures.

**NURSES AND NURSES’ AIDES**

- Dexamethasone sodium phosphate ophthalmic solution is contraindicated in lactating women. In case of exposure, patients should be instructed to avoid allowing the tip of the dispensing container to contact the eye or surrounding structures.

**CLINICAL PHARMACOLOGY**

- Dexamethasone sodium phosphate suppresses the inflammatory response to a variety of agents and is probably delayed or slowed healing. Its capacity to suppress the inflammatory response is proportional to the concentration of corticosteroids. The prolonged use of corticosteroids may result in the development of persistent fungal infections of the cornea. The possibility of fungal infections of the cornea should be considered after prolonged corticosteroid dosing. Dexamethasone sodium phosphate suppresses the inflammatory response to a variety of agents and it probably delays or slows healing. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in nonasthmatic people.

**MATERIALS HANDBOOK**

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**PATIENTS WITH ASTHMA**

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Nursing Mothers

Topically applied steroids are absorbed systemically. Therefore, because of the potential for serious adverse reactions in nursing infants from dexamethasone sodium phosphate, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS

Glaucoma with optic nerve damage, visual acuity and field defects, posterior subcapsular cataract formation, secondary ocular infection from pathogens including herpes simplex, perforation of the globe.

Rarely, filtering blebs have been reported when topical steroids have been used following cataract surgery.

Rarely, stinging or burning may occur.

DOSAGE AND ADMINISTRATION

The duration of treatment will vary with the type of lesion and may extend from a few days to several weeks, according to therapeutic response. Relapses, more common in chronic active lesions than in self-limited conditions, usually respond to retreatment.

Eye:

Instill one or two drops of solution into the conjunctival sac every hour during the day and every two hours during the night as initial therapy. When a favorable response is observed, reduce dosage to one drop every four hours. Later, further reduction in dosage to one drop three or four times daily may suffice to control symptoms.

Ear:

Clean the aural canal thoroughly and sponge dry. Instill the solution directly into the aural canal. A suggested initial dosage is three or four drops two or three times a day. If a favorable response is obtained, reduce dosage gradually and eventually discontinue. If preferred, the aural canal may be packed with a gauze wick saturated with solution. Keep the wick moist with the preparation and remove from the ear after 12 to 24 hours. Treatment may be repeated as often as necessary at the discretion of the physician.

HOW SUPPLIED

Dexamethasone Sodium Phosphate Ophthalmic Solution USP 0.1%, is supplied in a plastic squeeze bottle with a controlled drop tip in the following size: 5 mL - NDC 24208-720-02

Storage:

Store between 15°-25° C (59°-77° F).

DO NOT USE IF IMPRINTED NECKBAND IS NOT INTACT.

KEEP OUT OF REACH OF CHILDREN.

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