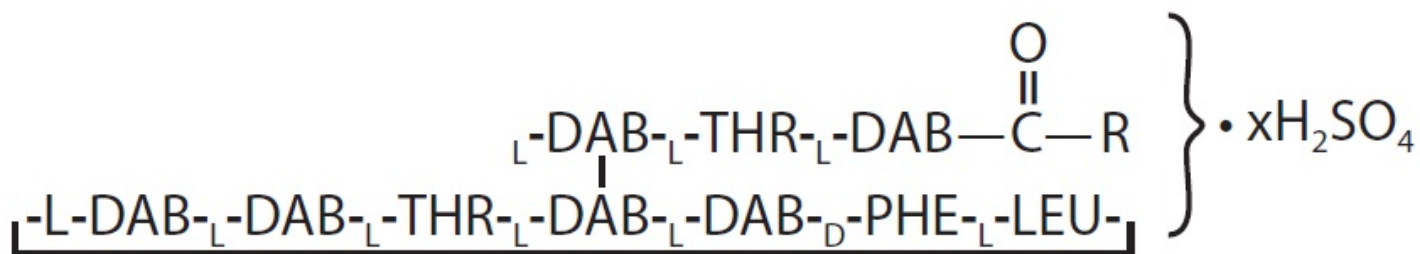


Polymyxin B Sulfate is the sulfate salt of polymyxin B₁ and B₂ which are produced by the growth of *Bacillus polymyxa* (Prazmowski) Migula (Fam. Bacillaceae). It has a potency of not less than 6,000 polymyxin B units per milligram, calculated on an anhydrous basis. The structural formula are:



(DAB = 2, 4 — diaminobutyric acid)

Polymyxin B₁ R = (+) — 5— methylheptyl

Polymyxin B₂ R = 5— methylhexyl

Each gram of ointment contains: ACTIVES: Dexamethasone 1 mg (0.1%), Neomycin Sulfate equivalent to Neomycin 3.5 mg base, Polymyxin B Sulfate 10,000 units in a base containing INACTIVES: White Petrolatum and Mineral Oil.

CLINICAL PHARMACOLOGY:

Corticoids suppress the inflammatory response to a variety of agents and they probably delay or slow healing. Since corticoids may inhibit the body's defense mechanism against infections, a concomitant antimicrobial drug may be used when this inhibition is considered to be clinically significant in a particular case. When a decision to administer both a corticoid 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 drugs 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.

INDICATIONS AND USAGE:

For steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where bacterial infection or risk of bacterial ocular infection exists.

Ocular steroids are indicated in inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe where the inherent risk of steroid use in certain infective conjunctivitis 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.

The particular anti-infective drugs in this product is active against the following common bacterial eye pathogens: *Staphylococcus aureus*, *Escherichia coli*, *Haemophilus influenzae*, *Klebsiella/Enterobacter* species, *Niesseria* species, and *Pseudomonas aeruginosa*.

This product does not provide adequate coverage against: *Serratia marcescens* and Streptococci, including *Streptococcus pneumoniae*.

CONTRAINDICATIONS:

Epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, and many other viral diseases of the cornea and conjunctiva. Mycobacterial infection of the eye. Fungal diseases of ocular structures. Hypersensitivity to a component of the medication. (Hypersensitivity to the antibiotic component occurs at a higher rate than for the other components.)

The use of these combinations is always contraindicated after uncomplicated removal of a corneal foreign body.

WARNINGS:

NOT FOR INJECTION. Do not touch tube tip to any surface, as this may contaminate the contents. Prolonged use may result in 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 steroids. In acute purulent conditions of the eye, steroids may mask infection or enhance existing infection. If these products are used for 10 days or longer, intraocular pressure should be routinely monitored even though it may be difficult in children and uncooperative patients.

Products containing neomycin sulfate may cause cutaneous sensitization. Employment of steroid medication in the treatment of herpes simplex requires great caution.

PRECAUTIONS:

The initial prescription and renewal of the medication order beyond 8 g 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 steroid dosing. Patients should be advised not to wear contact lenses if they have signs and symptoms of bacterial ocular infection.

PREGNANCY:

Pregnancy Category C:

Dexamethasone has been shown to be teratogenic in mice and rabbits following topical ophthalmic application in multiples of the therapeutic dose.

In the mouse, corticosteroids produce fetal resorptions and a specific abnormality, cleft palate. In the rabbit, corticosteroids have produced fetal resorptions and multiple abnormalities involving the head, ears, limbs, palate, etc. There are no adequate or well-controlled studies in pregnant women. Neomycin and polymyxin B sulfates and dexamethasone ophthalmic ointment should be used during pregnancy only if the potential benefit to the mother justifies the potential risk to the embryo or fetus. Infants born of mothers who have received substantial doses of corticosteroids during pregnancy should be observed carefully for signs of hypoadrenalism.

NURSING MOTHERS:

Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Because many drugs are excreted in human milk, caution should be exercised when neomycin and polymyxin B sulfates and dexamethasone ophthalmic ointment is administered to a nursing woman.

PEDIATRIC USE:

Safety and effectiveness in pediatric patients have not been established.

GERIATRIC USE:

No overall clinical differences in safety or effectiveness have been observed between the elderly and other adult patients.

ADVERSE REACTIONS:

Adverse reactions have occurred with steroid/anti-infective combination drugs which can be attributed to the steroid component, the anti-infective component, or the combination. Exact incidence figures are not available since no denominator of treated patients is available.

Reactions occurring most often from the presence of the anti-infective ingredients are allergic sensitizations. The reactions due to the steroid component are: elevation of intraocular pressure (IOP) with possible development of glaucoma, and infrequent optic nerve damage; posterior subcapsular cataract formation; and delayed wound healing.

Secondary Infection: The development of the secondary infection has occurred after use of combination containing steroids and antimicrobials. Fungal infections of the cornea are particularly prone to develop coincidentally with long-term applications of steroids. The possibility of fungal invasion must be considered in any persistent corneal ulceration where steroid treatment has been used. Secondary bacterial ocular infection following suppression of host responses also occurs.

To report SUSPECTED ADVERSE REACTIONS, contact Perrigo at 1-866-634-9120, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DOSAGE AND ADMINISTRATION:

Apply a small amount into the conjunctival sac(s) up to three or four times daily.

How to Apply neomycin and polymyxin B sulfates and dexamethasone ophthalmic ointment:

- 1. Tilt your head back.
- 2. Place a finger on your cheek just under your eye and gently pull down until a "V" pocket is formed between your eyeball and your lower lid.
- 3. Place a small amount (about 1/2 inch) of neomycin and polymyxin B sulfates and dexamethasone ophthalmic ointment in the "V" pocket. Do not let the tip of the tube touch your eye.
- 4. Look downward before closing your eye.

Not more than 8 g should be prescribed initially and the prescription should not be refilled without further evaluation as outlined in **PRECAUTIONS** above.

HOW SUPPLIED:

Neomycin and polymyxin B sulfates and dexamethasone ophthalmic ointment USP is supplied in 3.5 g (1/8 oz) sterile tamper evident tubes with ophthalmic tip.

3.5 GRAM in a TUBE/1 TUBE in a CARTON (53217-289-01)

Store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature].

Repackaged by

Aidarex Pharmaceuticals, LLC

Corona, CA 92880

PRINCIPAL DISPLAY PANEL - Label



SPL Image

NEOMYCIN AND POLYMYXIN B SULFATES AND DEXAMETHASONE

neomycin, polymyxin b sulfates, dexamethasone ointment

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:53217-289(NDC:0574-4160)
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Route of Administration OPTHALMIC

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXAMETHASONE (UNII: 7S5I7G3JQL) (DEXAMETHASONE - UNII:7S5I7G3JQL)	DEXAMETHASONE	1 mg in 1 g
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297)	NEOMYCIN	3.5 mg in 1 g
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	10000 [USP'U] in 1 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
MINERAL OIL (UNII: T5L8T28FGP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53217-289-01	1 in 1 CARTON	07/03/2014	
1		3.5 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA062938	07/03/2014	

Labeler - Aidarex Pharmaceuticals LLC (801503249)

Revised: 5/2017

Aidarex Pharmaceuticals LLC