

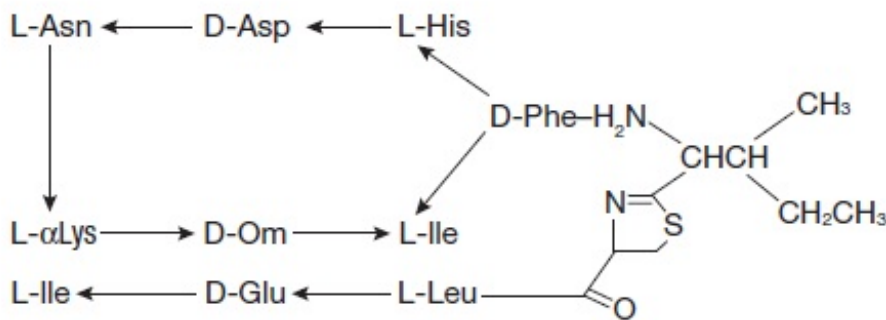
POLYCIN- bacitracin zinc and polymyxin b sulfates ointment
Padagis US LLC

Polycin®
bacitracin zinc and polymyxin B sulfate Ophthalmic Ointment USP
STERILE Rx Only

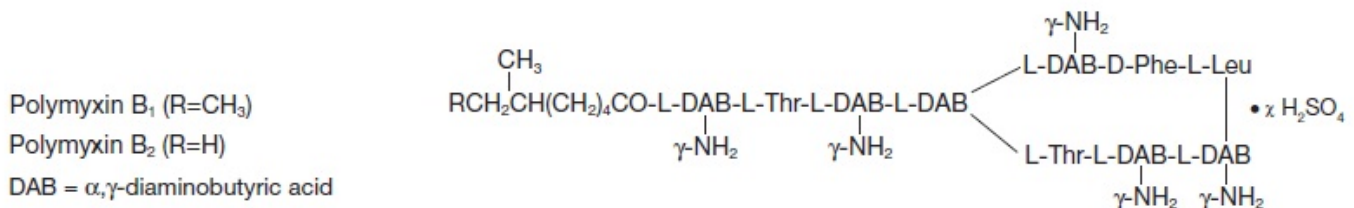
DESCRIPTION:

Bacitracin Zinc and Polymyxin B Sulfate Ophthalmic Ointment USP, is a sterile antimicrobial ointment for ophthalmic use. Each gram contains: bacitracin zinc equivalent to 500 bacitracin units, polymyxin B sulfate equivalent to 10,000 polymyxin B units, mineral oil, and white petrolatum.

Bacitracin zinc is the zinc salt of bacitracin, a mixture of related cyclic polypeptides (mainly bacitracin A) produced by the growth of an organism of the *licheniformis* group of *Bacillus subtilis* var Tracy. It has a potency of not less than 40 bacitracin units per mg. The structural formula for bacitracin A is:



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 mg, calculated on an anhydrous basis. The structural formulae are:



CLINICAL PHARMACOLOGY:

A wide range of antibacterial action is provided by the overlapping spectra of bacitracin

and polymyxin B sulfate. Bacitracin is bactericidal for a variety of gram-positive and gram-negative organisms. It interferes with bacterial cell wall synthesis by inhibition of the regeneration of phospholipid receptors involved in peptidoglycan synthesis. Polymyxin B is bactericidal for a variety of gram-negative organisms. It increases the permeability of the bacterial cell membrane by interacting with the phospholipid components of the membrane.

MICROBIOLOGY:

Bacitracin zinc and polymyxin B sulfate together are considered active against the following microorganisms: *Staphylococcus aureus*, streptococci including *Streptococcus pneumoniae*, *Escherichia coli*, *Haemophilus influenzae*, *Klebsiella/Enterobacter* species, *Neisseria* species and *Pseudomonas aeruginosa*. The product does not provide adequate coverage against *Serratia marcescens*.

INDICATIONS AND USAGE:

Polycin® Ophthalmic Ointment is indicated for the topical treatment of superficial infections of the external eye and its adnexa caused by susceptible bacteria. Such infections encompass conjunctivitis, keratitis and keratoconjunctivitis, blepharitis and blepharoconjunctivitis.

CONTRAINDICATIONS:

Polycin® Ophthalmic Ointment is contraindicated in individuals who have shown hypersensitivity to any of its components.

WARNINGS:

NOT FOR INJECTION INTO THE EYE. Bacitracin Zinc and Polymyxin B Sulfate Ophthalmic Ointment should never be directly introduced into the anterior chamber of the eye. Ophthalmic ointments may retard corneal wound healing. Topical antibiotics may cause cutaneous sensitization. A precise incidence of hypersensitivity reactions (primarily skin rash) due to topical antibiotics is not known. The manifestations of sensitization to topical antibiotics are usually itching, reddening, and edema of the conjunctiva and eyelid. A sensitization reaction may manifest simply, as a failure to heal. During long-term use of topical antibiotic products, periodic examination for such signs is advisable, and the patient should be told to discontinue the product if they are observed. Symptoms usually subside quickly on withdrawing the medication. Application of products containing these ingredients should be avoided for the patient thereafter (see **PRECAUTIONS: General**).

PRECAUTIONS:

General:

As with other antibiotic preparations, prolonged use of Bacitracin Zinc and Polymyxin B Sulfate Ophthalmic Ointment may result in overgrowth of non susceptible organisms

including fungi. If superinfection occurs, appropriate measures should be initiated. Bacterial resistance to Bacitracin Zinc and Polymyxin B Sulfate Ophthalmic Ointment may also develop. If purulent discharge, inflammation, or pain become aggravated, the patient should discontinue use of the medication and consult a physician.

There have been reports of bacterial keratitis associated with the use of topical ophthalmic products in multiple-dose containers which have been inadvertently contaminated by patients, most of whom has a concurrent corneal disease or a disruption of the ocular epithelial surface (see **PRECAUTIONS: Information for Patients**).

Allergic cross-reactions may occur which could prevent the use of any or all of the following antibiotics for the treatment of future infections: kanamycin, paromomycin, streptomycin, and possibly gentamicin.

Information for Patients:

Patients should be instructed to avoid allowing the tip of the dispensing container to contact the eye, eyelid, fingers, or any other surface. The use of this product by more than one person may spread infection.

Patients should also be instructed that ocular products, if 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 from using contaminated products (see **PRECAUTIONS: General**).

If the condition persists or gets worse, or if a rash or allergic reaction develops, the patient should be advised to stop use and consult a physician. Do not use this product if you are allergic to any of the listed ingredients. Keep tightly closed when not in use. Keep out of reach of children.

Carcinogenesis, Mutagenesis, Impairment of Fertility:

Long-term studies in animals to evaluate carcinogenic or mutagenic potential have not been conducted with polymyxin B sulfate or bacitracin. Polymyxin B has been reported to impair the motility of equine sperm, but its effects on male or female fertility are unknown. No adverse effects on male or female fertility, litter size, or survival were observed in rabbits given bacitracin zinc 100 gm/ton of diet.

Pregnancy:

Teratogenic Effects:

Pregnancy Category C.

Animal reproduction studies have not been conducted with polymyxin B sulfate or bacitracin. It is also not known whether Bacitracin Zinc and Polymyxin B Sulfate Ophthalmic Ointment can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Bacitracin Zinc and Polymyxin B Sulfate Ophthalmic Ointment should be given to a pregnant woman only if clearly needed.

Nursing Mothers:

It is not known whether this drug is excreted in human milk. Because many drugs are

excreted in human milk, caution should be exercised when Bacitracin Zinc and Polymyxin B Sulfate Ophthalmic Ointment is administered to a nursing woman.

Pediatric Use:

Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS:

Adverse reactions have occurred with the anti-infective components Bacitracin Zinc and Polymyxin B Sulfate Ophthalmic Ointment. The exact incidence is not known. Reactions occurring most often are allergic sensitization reactions including itching, swelling, and conjunctival erythema (see **WARNINGS**). More serious hypersensitivity reactions, including anaphylaxis, have been reported rarely. Local irritation on instillation has also been reported.

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:

May be applied every 3 or 4 hours for 7 to 10 days, depending on the severity of the infection.

HOW SUPPLIED:

Polycin® Ophthalmic Ointment is supplied in 3.5 g (1/8 oz) sterile tamper evident tubes with ophthalmic tip.

NDC 0574-**4021**-35

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

Polycin® is a Registered Trademark of Perrigo Company

Manufactured For Perrigo, Minneapolis, MN 55427

R1113

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6U200 RC J1

Rev 12-13 A

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL - Carton

Rx Only

NDC 0574-**4021**-35

STERILE

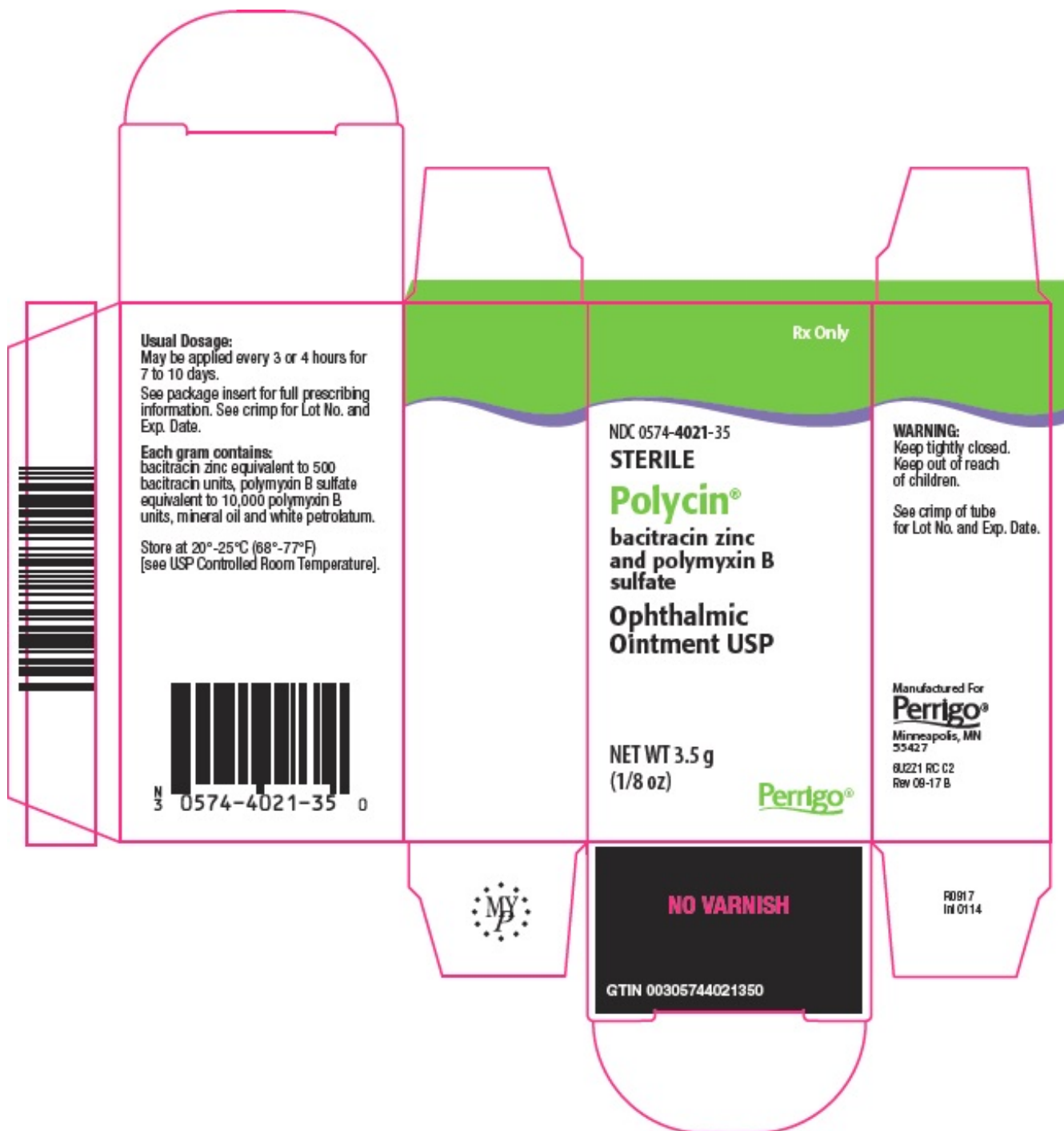
Polycin®

bacitracin zinc and polymyxin B sulfate

Ophthalmic Ointment USP

NET WT 3.5 g

(1/8 oz)



The following image is a placeholder representing the product identifier that is either affixed or imprinted on the drug package label during the packaging operation.

S/N [insert product's serial number]
 Lot [insert product's lot number]
 Exp [insert product's expiration date]

POLYCIN

bacitracin zinc and polymyxin b sulfates ointment

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0574-4021
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	500 [USP'U] in 1 g
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ.07J96K)	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:0574-4021-35	1 in 1 CARTON	11/12/2014	
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	ANDA065022	11/12/2014	

Labeler - Padagis US LLC (967694121)

