

MUPIROCIN- mupirocin ointment
Sun Pharmaceutical Industries, Inc.

Mupirocin
Ointment USP, 2%

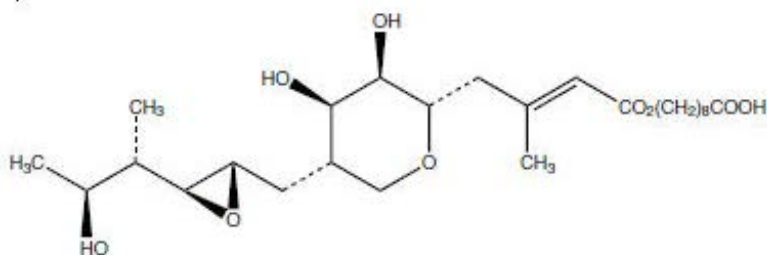
For dermatologic use on dogs

CAUTION

Federal law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION

Each gram of mupirocin ointment contains 20 mg of mupirocin in a bland, water-washable ointment base consisting of polyethylene glycol 400 and polyethylene glycol 3350 (polyethylene glycol ointment). Mupirocin is a naturally-occurring, broad-spectrum antibiotic. The chemical name is 9-4-[5S-(2S,3S-epoxy-5S-hydroxy-4S-methylhexyl)-3R,4R-dihydroxytetrahydropyran-2S-yl]-3-methylbut-2(E)-enoxy-nonanoic acid. The chemical structure is:



CLINICAL PHARMACOLOGY

Mupirocin is a chemical entity produced by fermentation of the organism *Pseudomonas fluorescens*. Mupirocin inhibits bacterial protein synthesis by reversibly and specifically binding to bacterial isoleucyl transfer-RNA synthetase. Due to this mode of action, mupirocin shows no cross resistance with chloramphenicol, erythromycin, gentamicin, lincomycin, neomycin, novobiocin, penicillin, streptomycin, and tetracycline. Mupirocin is an antimicrobial agent that inhibits the growth of gram-positive and gram-negative

bacteria.

Bacteria susceptible to the action of mupirocin *in vitro* include the aerobic isolates of *Staphylococcus aureus* (including methicillin-resistant strains and β -lactamase-producing strains), *Staphylococcus intermedius*, *Staphylococcus epidermidis*, other coagulase positive or negative Staphylococci, α -hemolytic Streptococci, β group A Streptococci (including *S. pyogenes*), other β Streptococci (including *S. agalactiae*), group D Streptococci (including *S. faecalis* and *S. faecium*), group Viridans Streptococci, *Streptococcus pneumoniae*, *Corynebacterium hofmannii*, *Bacillus subtilis*, *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis*, *Proteus vulgaris*, *Enterobacter cloacae*, *Enterobacter aerogenes*, *Citrobacter freundii*, *Hemophilus influenzae* (including β -lactamase-producing strains), *Neisseria gonorrhoeae* (including β -lactamase-producing strains), *Neisseria meningitidis*, *Branhamella catarrhalis* and *Pasteurella multocida*, and the anaerobic isolates of *Peptostreptococcus anaerobius*, *Clostridium difficile*, and *Clostridium sporogenes*.

Clinical significance of the *in vitro* data is unknown except for susceptible strains of *Staphylococcus aureus* and *Staphylococcus intermedius*.

INDICATIONS FOR USE

Mupirocin ointment is indicated for the topical treatment of canine bacterial infections of the skin, including superficial pyoderma, caused by susceptible strains of *Staphylococcus aureus* and *Staphylococcus intermedius*.

CONTRAINDICATIONS

This drug is contraindicated in animals with a history of sensitivity reactions to any of its components.

WARNINGS

Because of the potential hazard of nephrotoxicity due to the polyethylene glycol content of the base, care should be exercised when using this product in treating extensive deep lesions where absorption of large quantities of polyethylene glycol is possible.

Safety of use in pregnant or breeding animals has not been determined.

Mupirocin ointment is not for ophthalmic use.

ADVERSE REACTIONS

No adverse reactions have been reported with this product. If a skin reaction such as irritation should occur, treatment should be discontinued and appropriate therapy instituted.

DOSAGE AND ADMINISTRATION

Prior to treatment, the lesion should be cleansed. Mupirocin ointment should be applied to the affected area twice a day. Apply a sufficient amount of ointment to completely

cover the infected area. Maximum duration of treatment should not exceed 30 days.

HOW SUPPLIED

Mupirocin ointment is supplied in 5 g, 15 g, 22 g, and 30 g tubes.

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

Keep Out of Reach of Children

Approved by FDA under ANADA # 200-457

Mfd. by: Taro Pharmaceutical Industries Ltd.
Haifa Bay, Israel 2624761

Dist. by: **Taro Pharmaceuticals U.S.A., Inc.**
Hawthorne, NY 10532

Revised: November 2020

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PRINCIPAL DISPLAY PANEL - 22 g Tube Carton

NDC 51672-1354-0

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Ointment USP, 2%

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Net Weight
22 g

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TARO



MUPIROCIN

mupirocin ointment

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:51672-1354
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Mupirocin (UNII: D0GX8630A5) (Mupirocin - UNII:D0GX8630A5)	Mupirocin	20 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
polyethylene glycol 400 (UNII: B697894SGQ)	
polyethylene glycol 3350 (UNII: G2M7P15E5P)	

Product Characteristics

Color	WHITE (cream-like)	Score	
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Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51672-1354-5	1 in 1 CARTON		
1		5 g in 1 TUBE		
2	NDC:51672-1354-1	1 in 1 CARTON		
2		15 g in 1 TUBE		
3	NDC:51672-1354-0	1 in 1 CARTON		
3		22 g in 1 TUBE		
4	NDC:51672-1354-2	1 in 1 CARTON		
4		30 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200457	11/29/2010	

Labeler - Sun Pharmaceutical Industries, Inc. (146974886)

Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharma Canada Inc.		243339023	MANUFACTURE

Establishment

Name	Address	ID/FEI	Business Operations
Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd		654019884	API MANUFACTURE

Establishment

Name	Address	ID/FEI	Business Operations
Teva Pharmaceutical Works Private Limited Company		366709764	API MANUFACTURE

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceutical Industries Ltd.		600072078	MANUFACTURE

Revised: 9/2023

Sun Pharmaceutical Industries, Inc.