

MURICIN- mupirocin ointment Dechra Veterinary Products

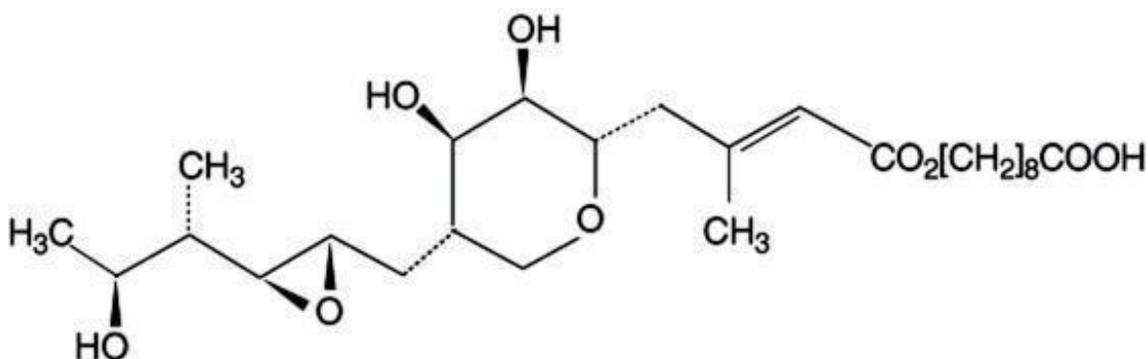
Muricin® (mupirocin ointment) 2%

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 Muricin 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, NF). Mupirocin is a naturally-occurring, broadspectrum antibiotic. The chemical name is (*E*)-(2*S*,3*R*,4*R*,5*S*)-5-[(2*S*,3*S*,4*S*,5*S*)-2,3-Epoxy-5-hydroxy-4-methylhexyl]tetrahydro-3,4-dihydroxy-β-methyl-2*H*-pyran-2-crotonic acid, ester with 9-hydroxynonanoic 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 hofmanii*, *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:

Muricin 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. Muricin 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.

To report suspected adverse drug events, for technical assistance, or to obtain a copy of the Safety Data Sheet, contact Dechra Veterinary Products at (866) 933-2472.

For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/reportanimalae>.

DOSAGE AND ADMINISTRATION:

Prior to treatment, the lesion should be cleansed. Muricin 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.

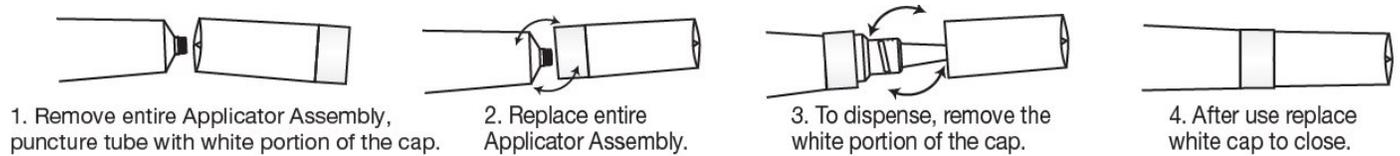
HOW SUPPLIED:

Muricin ointment is supplied in 15-gram tubes.

NDC 17033-420-15.

Store between 15° and 30°C (59° and 86°F).

Keep out of reach of children.



IMPORTANT:

The opening of this product is covered by a metal tamper-evident seal.

If this seal has been punctured or is not visible, do not use and return product to place of purchase.

Approved by FDA under ANADA # 200-418



Manufactured for:

Dechra Veterinary Products
Overland Park, KS 66211 USA

Manufactured by:

Fougera Pharmaceuticals Inc.
Melville, NY 11747 USA
46269504

Rev. December 2022

PRINCIPAL DISPLAY PANEL - 15 g Carton

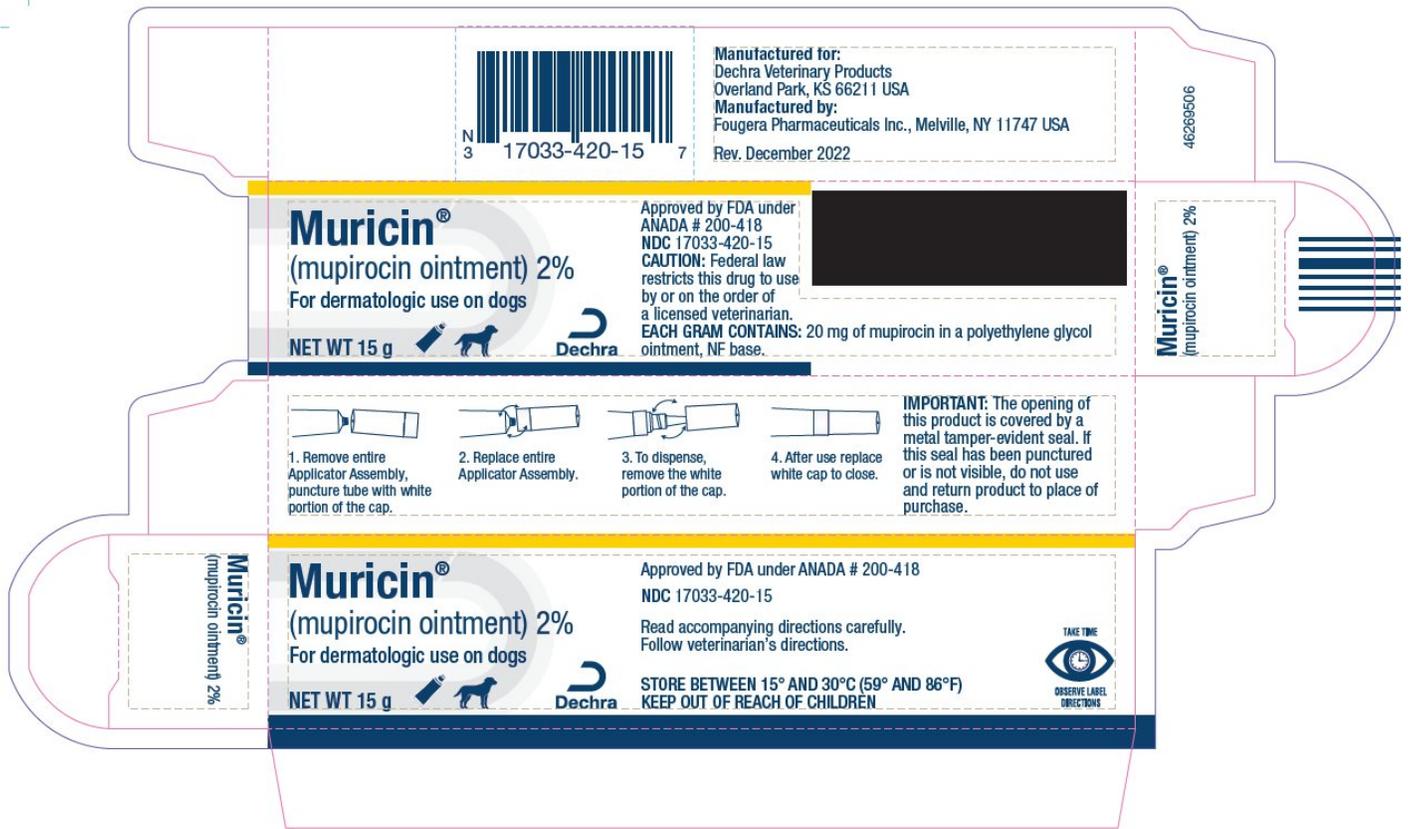
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(mupirocin ointment) 2%

For dermatologic use on dogs

NET WT 15 g

NDC 17033-420-15



MURICIN

mupirocin ointment

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:17033-420
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 3350 (UNII: G2M7P15E5P)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17033-420-15	1 in 1 CARTON		
1		15 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200418	03/08/2007	

Labeler - Dechra Veterinary Products (362142734)

Registrant - Fougera Pharmaceuticals Inc. (043838424)

Revised: 12/2022

Dechra Veterinary Products