

TRESADERM- dexamethasone, neomycin sulfate, and thiabendazole solution
Merial, Inc.

Tresaderm®
(thiabendazole, dexamethasone, neomycin sulfate solution)

NADA 042-633, Approved by the FDA.

1050-0030-01

Dermatologic Solution

CAUTION

Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION

Dermatologic Solution TRESADERM® (thiabendazole, dexamethasone, neomycin sulfate solution) contains the following active ingredients per mL: 40 mg thiabendazole, 1 mg dexamethasone, 3.2 mg neomycin (from neomycin sulfate). Inactive ingredients: glycerin, propylene glycol, purified water, hypophosphorous acid, calcium hypophosphite; about 8.5% ethyl alcohol and about 0.5% benzyl alcohol.

INDICATIONS

Dermatologic Solution TRESADERM is indicated as an aid in the treatment of certain bacterial, mycotic, and inflammatory dermatoses and otitis externa in dogs and cats. Both acute and chronic forms of these skin disorders respond to treatment with TRESADERM. Many forms of dermatosis are caused by bacteria (chiefly *Staphylococcus aureus*, *Proteus vulgaris* and *Pseudomonas aeruginosa*). Moreover, these organisms often act as opportunistic or concurrent pathogens that may complicate already established mycotic skin disorders, or otoacariasis caused by *Otodectes cynotis*. The principal etiologic agents of dermatomycoses in dogs and cats are species of the genera *Microsporum* and *Trichophyton*. The efficacy of neomycin as an antibacterial agent, with activity against both gram-negative and gram-positive pathogens, is well documented. Detailed studies in various laboratories have verified the significant activity thiabendazole displays against the important dermatophytes. Dexamethasone, a synthetic adrenocorticoid steroid, inhibits the reaction of connective tissue to injury and suppresses the classic inflammatory manifestations of skin disease. The formulation for TRESADERM combines these several activities in a complementary form for control of the discomfort and direct treatment of dermatitis and otitis externa produced by the above-mentioned infectious agents.

DOSAGE AND ADMINISTRATION

Prior to the administration of Dermatologic Solution TRESADERM, remove the ceruminous, purulent or foreign materials from the ear canal, as well as the crust which may be associated with dermatoses affecting other parts of the body. The design of the container nozzle safely allows partial insertion into the ear canal for ease of administration. The amount to apply and the frequency of treatment are dependent upon the severity and extent of the lesions. Five to 15 drops should be instilled in the ear twice daily. In treating dermatoses affecting other than the ear the surface of the lesions should be well moistened (2 to 4 drops per square inch) with Dermatologic Solution TRESADERM twice daily. The volume required will be dependent upon the size of the lesion.

Application of TRESADERM should be limited to a period of not longer than one week.

PRECAUTIONS

On rare occasions dogs may be sensitive to neomycin. In these animals, application of the drug will result in erythema of the treated area, which may last 24 to 48 hours. Also, evidence of transient discomfort has been noted in some dogs when the drug was applied to fissured or denuded areas. The expression of pain may last 2 to 5 minutes. Application of Dermatologic Solution TRESADERM should be limited to periods not longer than one week.

While systemic side effects are not likely with topically applied corticosteroids, such a possibility should be considered if use of the solution is extensive and prolonged. If signs of salt and water retention or potassium excretion are noticed (increased thirst, weakness, lethargy, oliguria, gastrointestinal disturbances or tachycardia), treatment should be discontinued and appropriate measures taken to correct the electrolyte and fluid imbalance.

Store in a refrigerator 36 - 46°F (2 - 8°C).

WARNING

For topical use in dogs and cats.

Avoid contact with eyes.

Keep this and all drugs out of the reach of children.

The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report adverse effects in users, to obtain an MSDS, or for assistance call 1-888-637-4251.

HOW SUPPLIED

Product 55871 - Dermatologic Solution TRESADERM Veterinary is supplied in 7.5 mL and 15 mL dropper bottles, each in 12 bottle boxes.

Marketed by

Merial, Inc.

Duluth, Georgia 30096-4640

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September 2015

TRESADERM is a registered trademark of Merial.

PRINCIPAL DISPLAY PANEL - 15 mL Bottle Carton

Tresaderm®

**(thiabendazole, dexamethasone,
neomycin sulfate solution)**

**Dermatologic Solution
for Dogs and Cats**

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12 x **15 mL** Bottles



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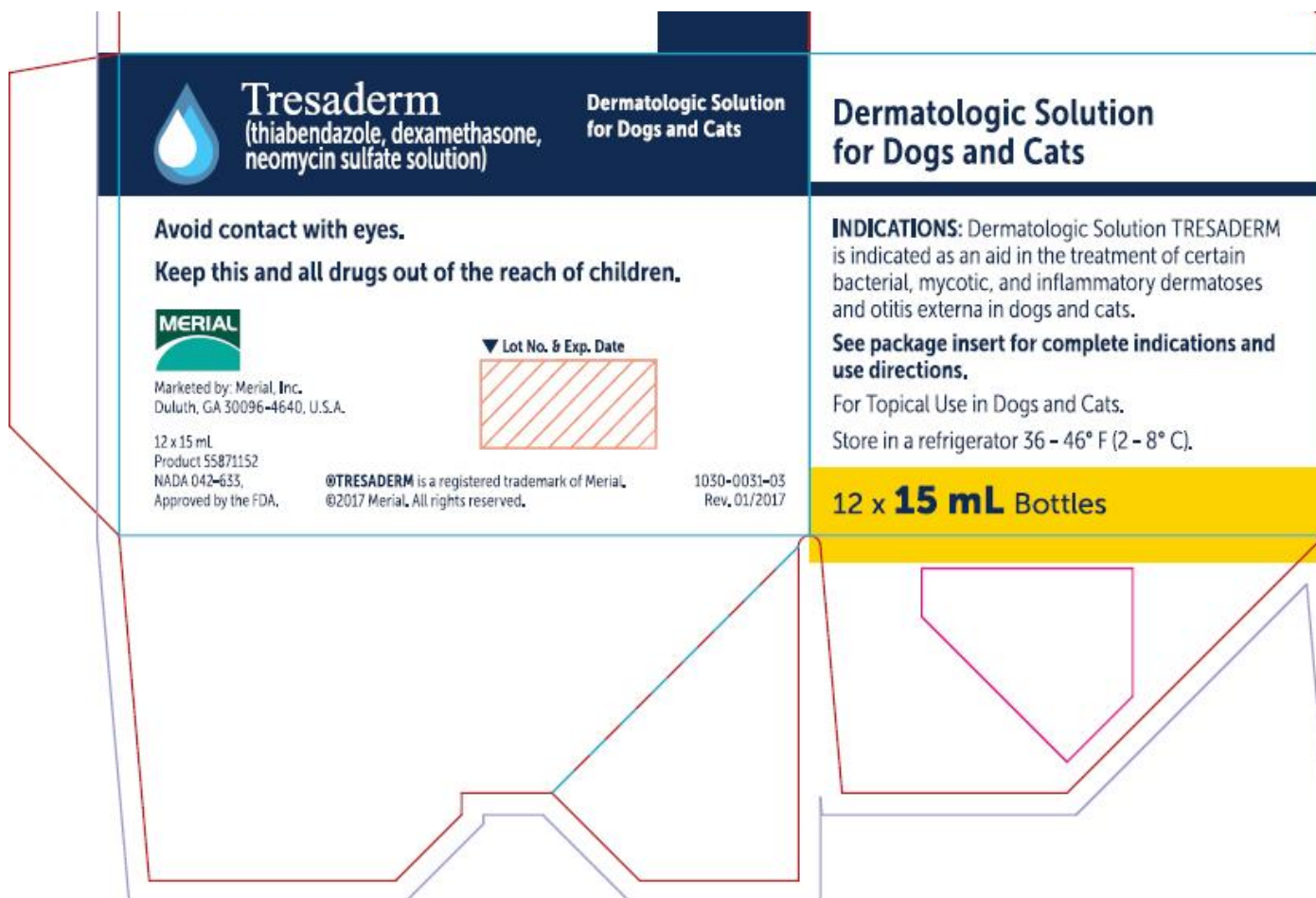
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Tresaderm®
(thiabendazole, dexamethasone,
neomycin sulfate solution)
Dermatologic Solution
for Dogs and Cats



Product 55871152



TRESADERM

dexamethasone, neomycin sulfate, and thiabendazole solution

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:50604-5587
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
dexamethasone (UNII: 7S5I7G3JQL) (dexamethasone - UNII:7S5I7G3JQL)	dexamethasone	1 mg in 1 mL
neomycin sulfate (UNII: 057Y626693) (neomycin - UNII:I16QD7X297)	neomycin	3.2 mg in 1 mL
thiabendazole (UNII: N1Q45E87DT) (thiabendazole - UNII:N1Q45E87DT)	thiabendazole	40 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
glycerin (UNII: PDC6A3C0OX)	
propylene glycol (UNII: 6DC9Q167V3)	
water (UNII: 059QF0KO0R)	
hypophosphorous acid (UNII: 8B1RL9B4ZJ)	
calcium hypophosphite (UNII: CUI83R2732)	

alcohol (UNII: 3K9958V90M)

benzyl alcohol (UNII: LKG8494WBH)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50604-5587-3	12 in 1 CARTON		
1	NDC:50604-5587-1	7.5 mL in 1 BOTTLE, WITH APPLICATOR		
2	NDC:50604-5587-4	12 in 1 CARTON		
2	NDC:50604-5587-2	15 mL in 1 BOTTLE, WITH APPLICATOR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA042633	11/09/1971	

Labeler - Merial, Inc. (799641006)

Revised: 5/2017

Merial, Inc.