

**TRESADERM- thiabendazole, dexamethasone, neomycin sulfate solution**  
**Boehringer Ingelheim Animal Health USA Inc.**

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

**Dermatologic Solution**

Approved by FDA under NADA # 042-633

**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 Safety Data Sheet (SDS) contains more detailed occupational safety information. To report suspected adverse drug events, for technical assistance, or to obtain a copy of the Safety Data Sheet (SDS), contact Boehringer Ingelheim Animal Health USA Inc. at 1-888-637-4251. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS, or online at [www.fda.gov/reportanimalae](http://www.fda.gov/reportanimalae).

## **HOW SUPPLIED**

Products 128740 & 128741 - Dermatologic Solution TRESADERM Veterinary is supplied in 7.5 mL and 15 mL dropper bottles, each in 12 bottle boxes.

Marketed by  
Boehringer Ingelheim Animal Health USA Inc.  
Duluth, Georgia 30096

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**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



# TRESADERM

thiabendazole, dexamethasone, neomycin sulfate solution

## Product Information

<b>Product Type</b>	PRESCRIPTION ANIMAL DRUG	<b>Item Code (Source)</b>	NDC:0010-5587
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>glycerin</b> (UNII: PDC6A3C00X)	
<b>propylene glycol</b> (UNII: 6DC9Q167V3)	
<b>water</b> (UNII: 059QF0KO0R)	
<b>hypophosphorous acid</b> (UNII: 8B1RL9B4ZJ)	
<b>calcium hypophosphite</b> (UNII: CUI83R2732)	
<b>alcohol</b> (UNII: 3K9958V90M)	
<b>benzyl alcohol</b> (UNII: LKG8494WBH)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0010-5587-02	12 in 1 CARTON		
1	NDC:0010-5587-01	7.5 mL in 1 BOTTLE, WITH APPLICATOR		
2	NDC:0010-5587-04	12 in 1 CARTON		
2	NDC:0010-5587-03	15 mL in 1 BOTTLE, WITH APPLICATOR		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA042633	11/03/2020	

**Labeler** - Boehringer Ingelheim Animal Health USA Inc. (007134091)