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

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.

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

October 2018

®TRESADERM is a registered trademark of Boehringer Ingelheim Animal Health USA Inc.

PRINCIPAL DISPLAY PANEL - 15 mL Bottle Carton

Tresaderm®
(thiabendazole, dexamethasone,neomycin sulfate solution)

Dermatologic Solutionfor Dogs and Cats

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

12 x **15 mL** Bottles

Tresaderm®

(thiabendazole, dexamethasone, neomycin sulfate solution)

Dermatologic Solution for Dogs and Cats

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

12 x **15 mL** Bottles

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Dermatologic Solution for Dogs and Cats

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Inactive Ingredients: glycerin, propylene glycol, purified water, hypophosphorous acid, calcium hypophosphite; about 8.5% ethyl alcohol and about 0.5% benzyl alcohol.

12 x **15 mL** Bottles

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

Product 128740

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

Avoid contact with eyes.

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

Manufactured by: Boehringer Ingelheim Animal Health USA INC., DULUTH, GA 30096

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12 x 15 mL
Product 128740
Approved by FDA
under NADA # 043-153

▼ Lot No. & Exp. Date

1050-0052-04
Rev. 10/2018

Boehringer Ingelheim

Dermatologic Solution for Dogs and Cats

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.

See package insert for complete indications and use directions.

For Topical Use in Dogs and Cats.

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

12 x **15 mL** Bottles

TRESADERM

thiabendazole, dexamethasone, neomycin sulfate solution

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:0010-5587
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: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)

Revised: 12/2020 Boehringer Ingelheim Animal Health USA Inc.