

TRESADERM®

Rx

Merial

Topical Antimicrobial-Corticosteroid

Thiabendazole-Dexamethasone-Neomycin Sulfate Solution

NADA No.: 042-633

Active Ingredient(s): Dermatologic solution TRESADERM® (thiabendazole-dexamethasone-neomycin sulfate solution) contains the following active ingredients per mL:

Thiabendazole	40 mg
Dexamethasone	1 mg
Neomycin (from neomycin sulfate)	3.2 mg

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 dermatoses are caused by bacteria (chiefly *Staphylococcus aureus*, *Proteus vulgaris* and *Pseudomonas aeruginosa*). These organisms often act as opportunistic or concurrent pathogens that may complicate already established mycotic skin disorders, or otoacariasis caused by *Otodectes cynotis*. The principle 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 TRESADERM® formulation 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 material 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 (5) to 15 drops should be instilled into the ear twice a day. 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 a day. The volume required will be dependent upon the size of the lesion.

TRESADERM® is limited to seven (7) days maximum duration of administration.

Precaution(s): Store in refrigerator (36-46°F).

Caution(s): Federal law restricts this drug to use by or on the order of a licensed veterinarian.

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 for 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 two to five 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, gastro-intestinal disturbances or tachycardia), treatment should be discontinued and appropriate measures taken to correct the electrolyte and fluid imbalance. Also, it should be remembered that TRESADERM® is not a hormonal replacement, hence it will have no effect on the alopecia of hypothyroidism. For topical use in dogs and cats.

Avoid contact with eyes. Keep out of the reach of children.

Presentation: 7.5 mL and 15 mL dropper bottles in boxes of 12.

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responsibility of the readers to familiarize themselves with the product information contained on the product label or package insert. Compendium Code No.: 08491039