

NADA 141-210, Approved by FDA

Genesis[®] TOPICAL SPRAY

Solution of 0.015% triamcinolone acetonide

FOR TOPICAL USE IN DOGS ONLY

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

DESCRIPTION

Genesis Topical Spray contains 0.015% triamcinolone acetonide for dermatologic use. Each mL of Genesis Topical Spray contains 0.15 mg triamcinolone

acetonide in an aqueous solution containing propylene glycol, specially denatured alcohol, and DMDM hydantoin.

PHARMACOLOGY

Triamcinolone acetonide is a highly potent synthetic glucocorticoid, which is primarily effective because of its anti-inflammatory activity. Topical corticosteroids can be absorbed from normal intact skin. Studies have demonstrated that topical preparations of triamcinolone have decreased plasma cortisol levels and suppressed the response to ACTH.

INDICATIONS

Genesis Topical Spray is indicated for the control of pruritus associated with allergic dermatitis in dogs.

DOSAGE AND ADMINISTRATION

Apply sufficient pump sprays to uniformly and thoroughly wet the affected areas while avoiding run-off of excess product. Avoid getting the spray in dog's eyes. Genesis Topical Spray should be administered twice daily for seven days, once daily for the next seven days, then every other day for an additional 14 days (28 days total).

To avoid overdosing the product, use the following table to determine the maximum number of pump sprays per treatment application. For mild pruritus or for small treatment surface areas, the number of pumps used should be less than this maximum amount.

Table 1. Maximum allowable dosage

Dog weight		Maximum number of pumps per single application*	Total maximum volume (mL) per 28 day treatment regimen
lb	kg		
11	5	4	101
22	10	7	176
33	15	11	277
44	20	15	378
55	25	19	478 (one 16-oz bottle)
66	30	22	554
77	35	26	655
88	40	30	756
99	45	33	832
110	50	37	932 (two 16-oz bottles)

*Using the recommended dosing regimen, there are two applications per day for the first week, one application per day for the second week and one application every other day for the last two weeks of treatment.

WARNINGS

User Safety: Wear gloves when applying the product. Spray in a well ventilated area. If the spray causes irritation to mucous membranes, discontinue use. **Keep this and all drugs out of reach of children.**

Animal Safety: Clinical and experimental data have demonstrated that corticosteroids administered orally or by injection to animals may induce the first stage of parturition if used during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis. Additionally, corticosteroids administered to dogs, rabbits, and rodents during pregnancy have resulted in cleft palates in offspring. Corticosteroids administered to dogs during pregnancy have also resulted in other congenital anomalies including deformed forelegs, phocomelia, and anasarca.

PRECAUTIONS

The safety of this product for dogs less than eight pounds or for dogs less than one year of age has not been evaluated. The safety of this product in breeding,

pregnant or lactating dogs has not been evaluated (see WARNINGS). The safety of long term or repeated use of this product (greater than 28 days) has not been evaluated. Prolonged use or overdosage of any corticosteroid may produce adverse effects. Because absorption of triamcinolone acetonide through topical application on the skin and by licking may occur, dogs receiving triamcinolone acetonide therapy should be observed closely for evidence of hypothalamic-pituitary-adrenal (HPA) axis suppression. When the product was applied at approximately 6 times the maximum allowable dose (100mL) once daily to normal skin of two dogs for five days, plasma cortisol levels were decreased after the first treatment and response to ACTH was reduced.

If adverse clinical signs are observed, treatment should be discontinued. Once the signs have disappeared, treatment can be resumed at a lower dose or frequency of application. If hypersensitivity to the product occurs, treatment should be discontinued and appropriate therapy instituted. In the presence of dermatological infections, use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, the corticosteroid should be discontinued until the infection has been adequately controlled.

ADVERSE REACTIONS

In a field study with Genesis Topical Spray, polyuria was reported in 3 of 57 dogs (5.3%) and polyphagia in 1 of 57 dogs (1.8%). Mild (within reference range) decreases in total leukocyte, lymphocyte and eosinophil counts were also reported. The following local reactions were reported in ≤ 3.6% of 110 dogs treated with Genesis Topical Spray or the product vehicle: aversion/discomfort, sneezing and watery eyes.

EFFECTIVENESS

In a 28-day field study to demonstrate the effectiveness of Genesis Topical Spray in controlling pruritus associated with allergic dermatitis in dogs under field conditions, 105 dogs with atopy, unspecified allergic dermatitis, flea allergy, and food allergy were treated with Genesis Topical Spray at the recommended use level or placebo. Results are shown in Table 2.

Table 2. Percent of cases considered treatment successes

Treatment	Percent success ¹
Genesis Topical Spray	35/54 = 64.8%*
Placebo	12/51 = 23.5%

¹Success = reduction in the level of severity by two or more grades in the investigator's overall evaluation from the pre-treatment to the post-treatment evaluation period.
*Significantly different from placebo at p < 0.05

STORAGE CONDITIONS

Store at room temperature, 15° - 30° C (59° - 86° F).

HOW SUPPLIED

Genesis Topical Spray is supplied in 8 ounce (237 mL) and 16 ounce (478 mL) bottles with spray applicators.

For technical information or to report adverse reactions, please call (800) 338-3659.

Made in the USA.



Distributed by:
Virbac AH, Inc.
Fort Worth, TX 76137

U.S. Patent No. 6,300,326
301751-01
Rev. 10/07

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