SKINGUARD RESTORE- chlorhexidine gluconate, climbazole, phytosphingosine s alicyloyl s hampoo

Vicar Operating Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

SkinGuard® Restore Shampoo

ACTIVE INGREDIENTS: Chlorhexidine Gluconate 3%, Climbazole 0.5%, Phytosphingosine Salicyloyl 0.05%.

INACTIVE INGREDIENTS: Water, Cocamidopropyl Hydroxysultaine, Decyl Glucoside, Capryloyl Glycine, PEG-120 Methyl Glucose Dioleate, Propylene Glycol, Triethanolamine, Phenoxyethanol, Sodium Hydroxide, Fragrance, Citric Acid.

PROPERTIES:SkinGuard® Restore is a formulation designed for the antiseptic cleansing of the skin of dogs and cats. It is soap-free and contains mild cleansing bases and moisturizers. **SkinGuard**® **Restore** also contains phytosphingosine, a pro-ceramide to help soothe skin irritations and support a healthy skin barrier.

INDICATIONS: For use on dogs and cats only. For the management of skin infections that are responsive to chlorhexidine and climbazole.

DIRECTIONS FOR USE: Wet the animal with warm water and apply **SkinGuard® Restore**. Massage into the wet hair coat. Allow to remain on the hair coat for 5 to 10 minutes before rinsing thoroughly with clean water. Repeat if needed. Shampoo 2 to 3 times per week, for 1 to 2 weeks, or as directed by your veterinarian. May be used as part of a management plan as recommended by your veterinarian.

CAUTIONS: For external use on dogs and cats only. Avoid contact with the eyes. In case of contact with eyes, rinse thoroughly and consult your veterinarian. If skin irritation occurs or increases, discontinue use and consult with your veterinarian.

WARNING: Keep out of the reach of children.

STORAGE CONDITIONS: Store at room temperature. Do not freeze.

Authorized for sale through licensed veterinarians only.

Distributed by Vicar Operating, Inc. Los Angeles, CA 90064

Manufactured for Ceva Animal Health, LLC Lenexa, KS 66215

Questions? Call us at 1-800-999-0297

PRINCIPAL DISPLAY PANEL - 8 ounce (237 mL) Bottle

Restore

CHLORHEXIDINE GLUCONATE 3%, CLIMBAZOLE 0.5%, PHYTOSPHINGOSINE SALICYLOYL 0.05%

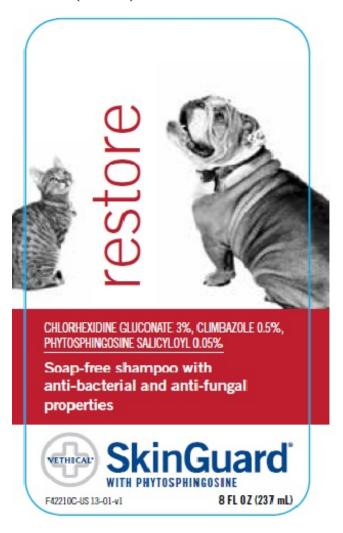
Soap-free shampoo with anti-bacterial and anti-fungal properties

VETHICAL

SkinGuard®

WITH PHYTOSPHINGOSINE

8 FL OZ (237 mL)



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F42210C-US 14-01-v2

SKINGUARD RESTORE

chlorhexidine gluconate, climbazole, phytosphingosine salicyloyl shampoo

Product Information Product Type OTC ANIMAL DRUG Item Code (Source) NDC:50386-1370 Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	30 mg in 1 mL	
CLIMBAZOLE (UNII: 9 N42CW7I54) (CLIMBAZOLE - UNII:9 N42CW7I54)	CLIMBAZOLE	5 mg in 1 mL	
SALICYLOYL PHYTOSPHINGOSINE (UNII: U891J4JCNH) (PHYTOSPHINGOSINE - UNII:GIN46U9Q2Q)	SALICYLOYL PHYTOSPHINGOSINE	.5 mg in 1 mL	

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

COCAMIDO PRO PYL HYDRO XYSULTAINE (UNII: 62V75NI93W)	
DECYL GLUCO SIDE (UNII: Z17H97EA6Y)	
CAPRYLOYL GLYCINE (UNII: 8TY5YO42NJ)	
PEG-120 METHYL GLUCOSE DIOLEATE (UNII: YM0K64F20V)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TROLAMINE (UNII: 9O3K93S3TK)	
PHENO XYETHANOL (UNII: HIE492ZZ3T)	
SO DIUM HYDRO XIDE (UNII: 55X0 4QC32I)	
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)	

ı	Packaging	ackaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
ı	1 NDC:50386-1370-1	237 mL in 1 BOTTLE, PLASTIC			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
unapproved drug other		12/20/2017			

Labeler - Vicar Operating Inc. (052503799)

Registrant - Ceva Sante Animale (261126049)

Revised: 12/2017 Vicar Operating Inc.