# SKINGUARD BALANCE MOUSSE- phytosphingosine hydrochloride liquid 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.

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#### SkinGuard® Balance Mousse

Soap-free mousse helps restore the skin's natural moisture balance and clear dryness and flakiness

ACTIVE INGREDIENT: Phytosphingosine HCl 0.2%

**INACTIVE INGREDIENTS:** Water, PEG/PPG/Polybutylene Glycol - 8/5/3 Glycerin, Glycerin, Panthenol, Sodium Lactate, Butylene Glycol, Capryl/Capramidopropyl Betaine, Polyglyceryl-10 Laurate, Dipropylene Glycol, Boswellia Serrata Gum Extract, Phenoxyethanol, Polyaminopropyl Biguanide, Fragrance.

**INDICATIONS:** For use on dogs and cats only. For the management of kerato-seborrheic conditions.

**DIRECTIONS FOR USE:** Shake well before use.

<u>For localized application:</u> Apply on dry hair. Brush the hair coat. Dispense 1 or 2 pumps in the hand and then apply on the targeted area, massage into the skin until fully penetrated. Do not rinse. Let air dry. Once dry, brush the hair coat again.

<u>For whole body application:</u> Apply on dry hair. Brush the hair coat. Dispense 1 or 2 pumps in the hand and then apply on the skin and hair. Massage into the skin until fully penetrated. Repeat as many times as necessary to cover the whole body, avoiding areas around the eyes and mouth. Do not rinse. Let air dry. Once dry, brush the hair coat again.

#### Dosage:

Under 11 lbs: 1 pump per 2 lbs

11-88 lbs: 1 pump per 4 lbs

Over 88 lbs: 1 pump per 6 lbs

Dosage can be doubled for long-haired breeds.

Apply every 3 days for 2 to 3 weeks or as recommended by your veterinarian. May be used in protocol with **SkinGuard**® **Balance Shampoo**, bathing on day 1 and applying the mousse on day 3 and day 6.

**CAUTIONS:** For external use on dogs and cats only. Avoid contact with the eyes. If contact with the eyes occurs, rinse thoroughly and consult your veterinarian. If skin irritation occurs or increases, discontinue use and consult 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 - 200 mL (6.8 OUNCE) BOTTLE

balance

## PHYTOSPHINGOSINE HCl 0.2%

Soap-free mousse helps restore the skin's natural moisture balance and clear dryness and flakiness

**VETHICAL®** 

SkinGuard®

WITH PHYTOSPHINGOSINE

200 ml (6.8 fl. oz.)



### PHYTOSPHINGOSINE HCI 0.2%

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6\_8 FL OZ (200 mL)

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F05010WCV

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F05010W-US 18-01-v2

# SKINGUARD BALANCE MOUSSE

phytosphingosine hydrochloride liquid

### **Product Information**

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:50386-1380
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
<b>PHYTOSPHINGOSINE HYDROCHLORIDE</b> (UNII: TT871XV7TU) (PHYTOSPHINGOSINE - UNII:GIN46U9Q2Q)	PHYTOSPHINGOSINE HYDROCHLORIDE	2 mg in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
CAPRAMIDO PRO PYL BETAINE (UNII: IQ93EE887Z)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
<b>PPG-3</b> (UNII: 3C8845E7C1)		
GLYCERIN (UNII: PDC6A3C0OX)		
PANTHENOL (UNII: WV9CM0O67Z)		
SODIUM LACTATE (UNII: TU7HW0W0QT)		
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)		
POLYGLYCERYL-10 LAURATE (UNII: MPJ2Q8WI8G)		
DIPROPYLENE GLYCOL (UNII: E107L85C40)		
BOSWELLIA SERRATA RESIN OIL (UNII: 5T1XCE6K8K)		
PHENO XYETHANO L (UNII: HIE49 2ZZ3T)		
POLYAMINO PRO PYL BIGUANIDE (UNII: 322U039 GMF)		

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50386-1380-1	200 mL in 1 BOTTLE, PLASTIC		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		11/16/2017		

# Labeler - Vicar Operating Inc. (052503799)

# Registrant - Ceva Sante Animale (261126049)

Revised: 11/2017 Vicar Operating Inc.