

SKINGUARD BALANCE- phytosphingosine hydrochloride shampoo
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® Balance Shampoo

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

ACTIVE INGREDIENT: Phytosphingosine HCl 0.1%.

INACTIVE INGREDIENTS: Water, Cocamidopropyl Betaine, Sodium Laureth Sulfate, Decyl Glucoside, Cyclopentasiloxane, Coco Glucoside, Coconut Alcohol, Acrylates/Steareth-20 Methacrylate Copolymer, Acrylates Copolymer, Triethanolamine, Polyquaternium-10, Phenoxyethanol, Polyperfluoromethylisopropyl Ether, Methylparaben, Fragrance, Polyquaternium-7, Methylchloroisothiazolinone, Methylisothiazolinone.

PROPERTIES: **SkinGuard® Balance** is a formulation designed to cleanse greasy and/or dry, scaly skin of dogs and cats. It is soap-free and contains moisturizers and film-forming agents to help maintain a normal production of sebum and skin cells. **SkinGuard® Balance** 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 kerato-seborrheic conditions.

DIRECTIONS FOR USE: Shake well before use. Wet the animal with warm water and apply **SkinGuard® Balance**. 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

balance

Phytosphingosine HCl 0.1%

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

SkinGuard®

VETHICAL®

WITH PHYTOSPHINGOSINE

8 FL OZ (237 mL)



PHYTOSPHINGOSINE HCl 0.1%

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



SkinGuard®
WITH PHYTOSPHINGOSINE

F42510E-US 13-01-v1

8 FL OZ (237 mL)

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F42510CCV

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F42510C-US 14-01-v2

SKINGUARD BALANCE

phytosphingosine hydrochloride shampoo

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:50386-1390
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHYTOSPHINGOSINE HYDROCHLORIDE (UNII: TT871XV7TU) (PHYTOSPHINGOSINE - UNII:GIN46U9Q2Q)	PHYTOSPHINGOSINE HYDROCHLORIDE	1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
SODIUM DECYLGLUCOSIDE HYDROXYPROPYLSULFONATE (UNII: B306V77S6R)	
COCO GLUCOSIDE (UNII: ICS790225B)	

COCONUT ALCOHOL (UNII: 13F4MW8Y9K)
CYCLOMETHICONE 5 (UNII: 0TH5PCI0R)
STEARETH-20 METHACRYLATE (UNII: A268NZ57NB)
TROLAMINE (UNII: 9O3K93S3TK)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
POLYQUATERNIUM-10 (400 CPS AT 2%) (UNII: HB1401PQFS)
ETHYL ACRYLATE/METHACRYLIC ACID/STEARETH-20 METHACRYLATE COPOLYMER (UNII: EPA1872R1N)
PERFLUOROPOLYMETHYLISOPROPYL ETHER (UNII: X6324K3MBW)
METHYL PARABEN (UNII: A2I8C7HI9T)
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600 KD) (UNII: 0L414VCS5Y)
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50386-1390-1	237 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/30/2017	

Labeler - Vicar Operating Inc. (052503799)

Registrant - Ceva Sante Animale (261126049)

Revised: 11/2017

Vicar Operating Inc.