

SKINGUARD RELIEVE- pramoxine hydrochloride, phytosphingosine salicyloyl 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® Relieve Shampoo

Soap-free shampoo that calms irritated skin and relieves itchiness

ACTIVE INGREDIENTS: Pramoxine HCl 1%, Phytosphingosine Salicyloyl 0.05%.

INACTIVE INGREDIENTS: Water, Sodium C14-16 Olefin Sulfonate, Cocamidopropyl Betaine, Disodium Cocoamphodiacetate, Glycerin, Sodium Lactate, Hydroxypropyl Methylcellulose, Tetrasodium EDTA, Fragrance, Hydrolyzed Oat Protein, Carthamus inctorius (Safflower) Seed Oil, Citric Acid, Sodium Chloride, Methylchloroisothiazolinone, Methylisothiazolinone.

PROPERTIES: SkinGuard® Relieve is a pleasantly scented formulation designed for the temporary relief of itching in dogs and cats. It is soap-free and contains mild cleansing bases. SkinGuard® Relieve contains pramoxine, a mild numbing agent, as well as colloidal oatmeal and essential fatty acids to further soothe irritated skin. SkinGuard® Relieve also contains phytosphingosine, a pro-ceramide to help support a healthy skin barrier.

INDICATION: For use on dogs and cats only. For the temporary relief of pruritus and skin irritations.

DIRECTIONS FOR USE: Shake well before use. Wet the animal with warm water and apply SkinGuard® Relieve. 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 2-3 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

relieve

PRAMOXINE HCl 1%, PHYTOSPHINGOSINE SALICYLOYL 0.05%

**Soap-free shampoo that calms
irritated skin and relieves itchiness**

VETHICAL®

SkinGuard®

WITH PHYTOSPHINGOSINE

8 FL. OZ. (237 mL)



PRAMOXINE HCl 1%,
PHYTOSPHINGOSINE SALICYLOYL 0.05%

**Soap-free shampoo that calms
irritated skin and relieves itchiness**



SkinGuard®
WITH PHYTOSPHINGOSINE

F41710E-US 13-01-v1

8 FL OZ (237 mL)

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F41710ECV

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F41710E-US 14-01-v2

SKINGUARD RELIEVE

pramoxine hydrochloride, phytosphingosine salicyloyl shampoo

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:50386-1340
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	10 mg in 1 mL
SALICYLOYL PHYTOSPHINGOSINE (UNII: U891J4JCNH) (PHYTOSPHINGOSINE - UNII:GIN46U9Q2Q)	SALICYLOYL PHYTOSPHINGOSINE	0.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	

DISODIUM CO CO AMPHODIACETATE (UNII: 18L9G3U51M)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM LACTATE (UNII: TU7HW0W0QT)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
EDETATE SODIUM (UNII: MP1J8420LU)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
OATMEAL (UNII: 8PI54V663Y)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50386-1340-1	237 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/06/2017	

Labeler - Vicar Operating Inc. (052503799)

Registrant - Ceva Sante Animale (261126049)

Revised: 12/2017

Vicar Operating Inc.