

**SKINGUARD RELIEVE MOUSSE- pramoxine hydrochloride, phytosphingosine salicyloyl 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® Relieve Mousse**

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

**ACTIVE INGREDIENT:** Pramoxine HCl 1%, Phytosphingosine Salicyloyl 0.05%.

**INACTIVE INGREDIENTS:** Water, Glycerin, PEG-8 Dimethicone, Polysorbate 80, Poloxamer 184, Sodium Lactate, Hydrolyzed Oat Protein, Fragrance, Aloe Barbadensis (Aloe) Leaf Extract, Methylisothiazolinone.

**PROPERTIES:** SkinGuard® Relieve is a formulation designed for the temporary relief of itching in dogs and cats without bathing. It is soap-free, alcohol-free and moisturizing. SkinGuard® Relieve also contains phytosphingosine, a pro-ceramide to help support a healthy skin barrier.

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

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

For localized application: 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.

For whole body application: 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 may be doubled for long-haired breeds.

Apply every 3 days for 2 to 3 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 - 6.8 OUNCE (200 mL) Bottle

relieve

PRAMOXINE HCl 1%,

PHYTOSPHINGOSINE SALICYLOYL 0.05%

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

Vethical®

SkinGuard®

WITH PHYTOSPHINGOSINE

6.8 FL OZ (200 mL)



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PHYTOSPHINGOSINE SALICYLOYL 0.05%

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F41620BCV

F41620B-US 18-L1-v2

## SKINGUARD RELIEVE MOUSSE

pramoxine hydrochloride, phytosphingosine salicyloyl liquid

### Product Information

<b>Product Type</b>	OTC ANIMAL DRUG	<b>Item Code (Source)</b>	NDC:50386-1420
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0K00R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PEG-8 DIMETHICONE</b> (UNII: GIA7T764OD)	
<b>SODIUM LACTATE</b> (UNII: TU7HW0W0QT)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>POLOXAMER 184</b> (UNII: BIS92ZSF57)	
<b>OAT</b> (UNII: Z6J799EAJK)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>METHYLISOTHIAZOLINONE</b> (UNII: 229D0E1QFA)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50386-1420-1	200 mL in 1 BOTTLE, PLASTIC		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/04/2017	

**Labeler** - Vicar Operating Inc (052503799)

**Registrant** - Ceva Sante Animale (261126049)

Revised: 12/2017

Vicar Operating Inc