DERMAL-SOOTHE- pramoxine hydrochloride cream Vetoquinol USA, 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.

Dermal-Soothe™

Patented Continuous Moisture Release

INDICATIONS:

An itch relieving, moisturizing cream rinse for application after shampooing. May be used on normal, dry or sensitive skin to provide itch relief, lasting moisture and coat luster. May be used with other medicated shampoos as directed by your veterinarian.

DESCRIPTION:

Micro Pearls[®] Advantage Dermal-SootheTM Anti-Itch Cream Rinse is a remarkable breakthrough in animal care technology. Dermal-SootheTM Anti-Itch Cream Rinse contains itch-relieving Pramoxine Hydrochloride and Novasome[®] microvesicles designed to deliver long lasting moisture factors to the hair and epidermal layers in a rich cream rinse base that relieves itching, dry skin and leaves the hair coat soft, supple and lustrous.

DIRECTIONS:

Remove foil seal prior to use. Shake well. Apply a liberal amount after shampooing. Work into coat and let stand for 10-15 minutes and then rinse thoroughly. As with any medicated topical product, gloves should be worn when applying this product.

ACTIVE INGREDIENTS:

Pramoxine Hydrochloride 1%

INACTIVE INGREDIENTS:

Cetyl Alcohol, Citric Acid Monohydrate, Collagen, Dimethicone, Fragrance, Glycol Stearate, Myristalkonium Chloride, NM3, Oatmeal, PEG-100 Stearate, Quaternium 15, Skin Respiratory Factor, Sodium Stearoamphoacetate, Water

PRECAUTIONS:

For topical use only on dogs, cats and horses. Avoid contact with eyes and mucous membranes. Discontinue use if skin becomes irritated or inflamed.

AVAILABLE ONLY THROUGH LICENSED VETERINARIANS. KEEP OUT OF REACH OF CHILDREN. FOR ANIMAL USE ONLY.

Novasome[®] is a registered trademark of Micro Pak, Inc.

QUESTIONS?

Manufactured for:

Vetoquinol USA, Inc. Ft. Worth, TX (USA) 76137 1 (800) 267-5707 www.vetoquinolusa.com

422628

4

Lot

Exp. Date

PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label

NDC 17030-042-16

vetoquinoL

MICRO PEARLS® ADVANTAGE

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 $\begin{array}{c} \mathsf{DERMAL}\text{-}\mathsf{SOOTHE^{\scriptscriptstyle\mathsf{TM}}}\\ \mathsf{CREAM}\;\mathsf{RINSE} \end{array}$

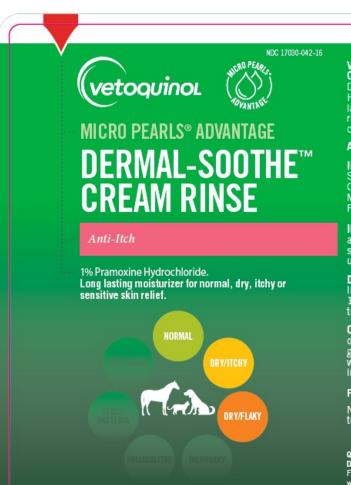
Anti-Itch

1% Pramoxine Hydrochloride.

Long lasting moisturizer for normal, dry, itchy or sensitive skin relief.

NORMAL DRY/ITCHY DRY/FLAKY

NET CONTENTS: 16 fl oz (473mL)



Vetoquinol Micro Pearls® Advantage Dermal-Soothe™ Anti-Itch Cream Rinse is a remarkable breakthrough in animal care technology. Dermal-Soothe™ Anti-Itch Cream Rinse contains itch-relieving Pramoxine Hydrochloride and Novasome® microvesicles designed to deliver long lasting moisture factors to the hair shafts and epidermal layers in a rich cream rinse base that relieves itching, dry skin and leaves the hair coat soft, supple and lustrous.

ACTIVE INGREDIENTS: Pramoxine Hydrochloride 1%.

INACTIVE INGREDIENTS: USP Purified Water, NM3, PEG-100, Sodium Stearoamphoacetate, Oatmeal, Glycol Stearate, Collagen, Cetyl Alcohol, Dimethylpolysiloxane, Fragrance, Quaternium 15, Myristalkonium Chloride & Quat 14, Citric Acid, Skin Respiratory Factor.

INDICATIONS FOR USE: An itch relieving, moisturizing cream rinse for application after shampooing. May be used on normal, dry or sensitive skin to provide itch relief, lasting moisture and coat luster. May be used with other medicated shampoos as directed by your veterinarian.

DIRECTIONS: Remove foil seal prior to use. Shake well. Apply a liberal amount after shampooing. Work into coat and let stand for 10-15 minutes and then rinse thoroughly. As with any medicated topical product, gloves should be worn when applying this product.

CAUTION: For topical use only on dogs, cats and horses. Keep out of the reach of children and animals. This product should not be given to animals intended for human consumption. Avoid contact with eyes and mucous membranes. Discontinue use if skin becomes irritated or inflamed.

FOR ANIMAL USE ONLY.

Novasome[®] is a registered trademark of Micro Pak, Inc.

QUESTIONS? Distributed by Vetoquinol USA Inc. Ft. Worth, TX (USA) 76137 www.vetoquinolusa.com 1 (800) 267-5707



NET CONTENTS: 16 fl oz (473mL)

DERMAL-SOOTHE

pramoxine hydrochloride cream

Product Information

Product Type OTC ANIMAL DRUG Item Code (Source) NDC:17030-042

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

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Citric Acid Monohydrate (UNII: 2968 PHW8 QP)	
Oatmeal (UNII: 8PI54V663Y)	
Dimethicone (UNII: 92RU3N3Y1O)	

Pork Collagen (UNII: 18442U2G7J)	
PEG-100 Stearate (UNII: YD01N1999R)	
Glycol Stearate (UNII: 0324G66D0E)	
Cetyl Alcohol (UNII: 936JST6JCN)	
Sodium Stearoamphoacetate (UNII: 19 MO 470 Z8 J)	
Myristalkonium Chloride (UNII: 0W255OL75T)	
Quaternium-15 (UNII: E40 U0 3LEM0)	

Product Characteristics			
Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17030-042-08	237 mL in 1 BOTTLE, PLASTIC		
2	NDC:17030-042-16	474 mL in 1 BOTTLE, PLASTIC		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		12/29/1999	

Labeler - Vetoquinol USA, Inc. (106824209)

Establishment			
Name	Address	ID/FEI	Business Operations
American Pharmaceuticals and Cosmetics, Inc.		038023805	MANUFACTURE

Establishment			
Name	Address	ID/FEI	Business Operations
Syn-Tech Chem. & Pharm. Co., Ltd.		656002532	API MANUFACTURE

Revised: 10/2018 Vetoquinol USA, Inc.