DERMAL-SOOTHE- pramoxine hydrochloride shampoo 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:

A luxurious conditioning shampoo for relieving itching and dry skin. Excellent for use on animals with normal, dry or sensitive skin.

DESCRIPTION:

Micro Pearls[®] Advantage Dermal-Soothe[™] Anti-Itch Shampoo is a remarkable breakthrough in animal care technology. Dermal-Soothe[™] Anti-Itch Shampoo contains itch-relieving Pramoxine Hydrochloride and Novasome[®] microvesicles designed to deliver long lasting moisture factors to the hair shafts and epidermal layers in a luxurious shampoo. The result is an itch-relieving shampoo that leaves your pet with a coat that is soft, supple and lustrous.

DIRECTIONS:

Remove foil seal prior to use. Shake well. Wet coat thoroughly before applying shampoo. Work into coat until a mild lather is produced. Allow to stand for 10-15 minutes and rinse thoroughly. As with any medicated topical product, gloves should be worn when applying this product.

ACTIVE INGREDIENTS:

Pramoxine Hydrochloride 1%

INACTIVE INGREDIENTS:

USP Purified Water, Decyl Polyglucose, Cocamidopropyl Hydroxysultaine, NM7, Cocamidopropyl Betaine, Ammonium Laureth Sulfate, Cetyl Alcohol, PEG 75 Lanolin, Hydrolyzed Keratin, Colloidal Oatmeal, Glycol Stearate, Citric Acid, Fragrance, Methylchloroisothiazolinone, Methylisothiazolinone and Skin Respiratory Factor.

CAUTIONS:

For topical use only on dogs, cats and horses. Avoid contact with eyes and mucous

membranes. Discontinue use if skin becomes irritated or inflamed.

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

422629

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Lot

Exp. Date

PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label

NDC 17030-040-16

vetoquinoL

MICRO PEARLS[®] ADVANTAGE

MICRO PEARLS[®] ADVANTAGE

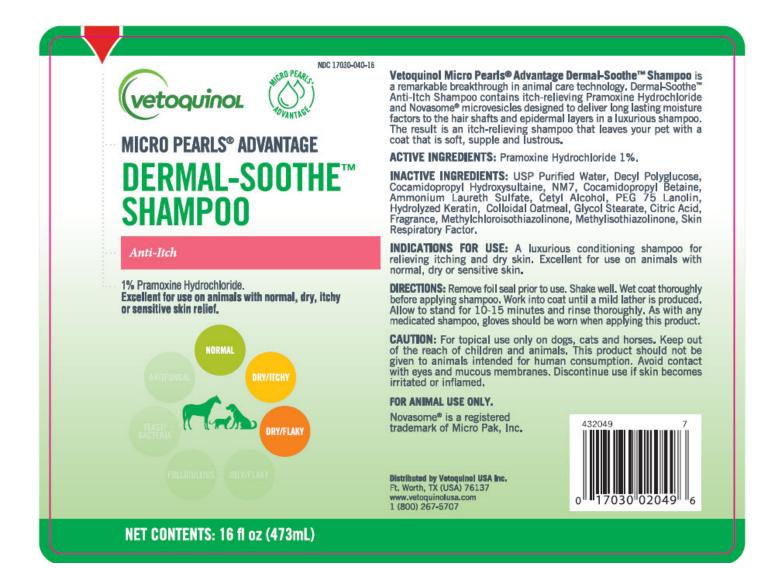
DERMAL-SOOTHE[™] SHAMPOO

Anti-Itch

1% Pramoxine Hydrochloride. Excellent for use on animals with normal, dry, itchy or sensitive skin relief.

NORMAL DRY/ITCHY DRY/FLAKY

NET CONTENTS: 16 fl oz (473mL)



DERMAL-SOOTHE

pramoxine hydrochloride shampoo

Product Information					
Product Type	OTC ANIMAL DRUG	Item Code (S	Source)	NDC:1	7030-040
Route of Administration	TOPICAL				
Active Ingredient/Active	Moiety				
	dient Name		Basis of Stre	ngth	Strength
Pramoxine Hydrochloride (UNII: UNII:068X84E056)	88AYB867L5) (Pramoxine -		Pramoxine Hydrochloride	-	10 mg in 1 mL
Inactive Ingredients					
	Ingredient Name				Strength
Water (UNII: 059QF0K00R)					
	ne (UNII: 62V75NI93W)				
Cocamidopropyl Hydroxysultai					

Ammonium Laureth-2	2 Sulfate (UN	NII: 69804Z48G6)					
Cetyl Alcohol (UNII: 93	36JST6JCN)						
PEG-75 Lanolin (UNII:	091790X7TE	3)					
Oatmeal (UNII: 8PI54V	663Y)						
Glycol Stearate (UNII:	0324G66D08	E)					
Citric Acid Monohydr	ate (UNII: 29	68PHW8QP)					
METHYLCHLOROISOT	HIAZOLINO	NE (UNII: DEL7T5QRP	N)				
Product Charact	eristics						
Color		WHITE	Score				
Shape			Size				
Flavor			Imprint Cod	e			
Contains							
Packaging							
# Item Code	Packad	ge Description	Marketing	g Start Date	Mark	eting Er	nd Date
1 NDC:17030-040-08	-	BOTTLE, PLASTIC		j etait 2410		<u>9</u>	
2 NDC:17030-040-16		BOTTLE, PLASTIC					
Marketing In	formati	on					
Marketing Category	Applicat	tion 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
Syn-Tech Chem. & Pharm. Co., Ltd.		656002532	API MANUFACTURE

Establishment

Name	Address	ID/FEI	Business Operations
Tropichem Research Labs, LLC dba Vetio		603123068	MANUFACTURE

Revised: 12/2021

Vetoquinol USA, Inc.