CERASOOTHE P ANTI-ITCH MOUSSE- pramoxine hydrochloride liquid Butler Animal Health Supply, LLC dba Covetrus North America

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.

CeraSoothe PRAMOXINE

Anti-itch Mousse

Fragrance: Cucumber melon

Formulated for cats, dogs, and horses

A leave-on mousse with pramoxine to help relieve itching and skin irritations. Ceramides and avenanthramides are skin nourishing nutriients that moisturize and calm the skin. The also support the skin's natural immune system and provide building blocks for renewed skin barrier integrity.

Active ingredients: Pramoxine HCl 1%.

Inactive ingredients: Water, glycerin, PEG-8 dimethicone, polysorbate 80, poloxamer 184, sodium lactate, aloe barbadensis (aloe) leaf juice, avena sativa (oat) kernel extract, ceramide EOP, ceramide EOS, ceramide NP, fragrance, potassium sorbate, methylisothiazolinone.

Indications: For use on cats, dogs and horses for the temporary relief of itching and skin irritations.

Directions for use: Brush the fur then apply product on dry hair. Apply every 3 days for 2-3 weeks or as directed by your veterinarian. Wash hands after use.

<u>For localized application</u>: Dispense 1 - 2 pumps onto your palm, then apply on the targeted area(s). Massage into the skin until fully penetrated. Do not rinse, let air dry. Once dry, brush the fur again.

<u>For whole body application</u>: Dispense 1 or 2 pumps onto your palm, then apply on the skin and hair. Massage into the skin until fully penetrated. Repeat as necessary to cover the whole body, avoiding the eyes and mouth. Do not rinse, let air dry. Once dry, brush the fur again.

<u>Dosage:</u>

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 dogs.

For deeper cleansing, use Ceraven Pramoxine anti-itch shampoo.

Cautions: For external use on cats, dogs or horses only. Avoid contact with 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.

Storage: Store at room temperature. Do not freeze.

QUESTIONS?

(855) 724-3461 Distributed by: Covetrus North America 400 Metro Place North Dublin, OH 43017 **covetrus.com**

PRINCIPAL DISPLAY PANEL - 6.8 OUNCE (200 mL) Bottle

Inspired by veteriarians

CeraSoothe PRAMOXINE

Anti-itch Mousse

Fragrance: Cucumber melon

Pramoxine HCl 1%

Formulated for cats, dogs, and horses

Keep out of reach of children

For animal use only

NDC: 11695-6985-1

Net Contents: 6.8 fl oz (200 mL)

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Inspired by veterinarians



Anti-Itch Mousse

Fragrance: Cucumber melon

Pramoxine HCI 1%



Formulated for cats, dogs, and horses

Keep out of reach of children For animal use only



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Active Ingredient: Pramoxine HCI 1%.

Inactive Ingredients: Water, glycerin, PEG-8 dimethicone, polysorbate 80, poloxamer 184, sodium lactate, aloe barbadensis (aloe vera) leaf juice, avena sativa (oat) kernel extract, ceramide EOP, ceramide EOS, ceramide NP, fragrance, potassium sorbate, methylisothiazolinone.

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Reorder #073118 D

Questions? Co (855) 724-3461 Di AH-073118-02 Co REV: 0621 Co

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G41410C-US 18-L1-v4

CERASOOTHE PANT		E				
Product Information						
Product Type	OTC ANIMAL DRUG	Item Code (Source) NDC:11695-6985		95-6985		
Route of Administration	TOPICAL					
Active Ingredient/Active	Moiety					
Ingred	lient Name		Basis of Str	ength	Strength	
RAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - NII:068X84E056)		KINE -	PRAMOXINE HYDROCHLORIDE		10 mg in 1 mL	
Inactive Ingredients						
Ingredient Name				Strength		
WATER (UNII: 059QF0KO0R)						

GLYCERIN (UNII: PDC6A3C0OX)

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PEG-8 DIMETHICON	E (UNII: GIA7T764OD)				
POLYSORBATE 80 (L	JNII: 60ZP39ZG8H)				
POLOXAMER 184 (UI	NII: BIS92ZSF57)				
ALOE VERA LEAF (UN	III: ZY81Z83H0X)				
VENANTHRAMIDES	(UNII: 5PA41O4AIT)				
CERAMIDE 1 (UNII: 51	FHT33P7X7)				
CERAMIDE EOS (UNII	: CR0J8RN66K)				
CERAMIDE NP (UNII:	4370DF050B)				
OTASSIUM SORBAT	FE (UNII: 1VPU26JZZ4)				
METHYLISOTHIAZOL	INONE (UNII: 229D0E1QFA)				
Packaging					
# Item Code	Package Description	Marketing Start Date		Marketing End Date	
L NDC:11695-6985-1	200 mL in 1 BOTTLE, PLASTIC				
Markating	formation				
Marketing Ir	iformation				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date		Marketing End Date
	Citation		Date		Date
inapproved drug			04/22/2021		
other					

Labeler - Butler Animal Health Supply, LLC dba Covetrus North America (603750329)

Registrant - Ceva Sante Animale (261126049)

Revised: 5/2022

Butler Animal Health Supply, LLC dba Covetrus North America