SUFFUSION P PS MOUSSE- pramoxine hydrochloride, phytosphingosine salicyloyl liquid Aspen Veterinary Resource, LTD.

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.

Pramosoothe +PS Mousse

ACTIVE INGREDIENTS: Pramoxine HCl 1%, Phytosphingosine Salicloyl 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: Pramosoothe +PS Mousse is designed for the temporary relief of itching without rinsing. It contains praamoxine, a mild numbing agent, as well as colloidal oatmeal to soothe irritated skin. It also contains phytosphingosine, a pro-ceramide to moisturize and help support a healthy skin barrier.

INDICATIONS: For the temporary relief of pruritus and skin irritations in dogs and cats.

DIRECTIONS FOR USE: Shake well before use. Brush the fur and then apply on dry hair. Apply every 3 days for 2-3 weeks or as directed by your veterinarian.

<u>For localized application</u>:Dispense 1 or 2 pumps onto your palm and 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 and then apply on the skin and hair. Massage gently 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 fur again.

Dosage:

Under 11 lbs: 1 pump per 2 lbs 12-88 lbs: 1 pump per 4 lbs Over 88 lbs: 1 pump per 6 lbs

Dosage may be doubled for long-haired dogs.

CAUTIONS: For external use on dogs and cats only. Avoid contact with eyes. If eye contact occurs, rinse thoroughly and consult your veterinarian. If skin irritation occurs or increases, discontinue use and consult with your veterinarian. Wash hands after use.

WARNING: Keep out of reach of children.

STORAGE CONDITIONS: Store at room temperature. Do not freeze.

QUESTIONS? 1-800-999-0297

Pivetal

Distributed by: Aspen Veterinary Resources , LTD. Liberty, MO 64068 www.pivetalvet.com

PRINCIPAL DISPLAY PANEL - 6.8 OUNCE (200 mL) Bottle

NDC 46066-165-14

SUFFUSIONTM

P +PS Mousse

Pramoxine HCl 1%, Phytosphingosine Salicloyl 0.05%

Soothing Mousse

FOR CATS & DOGS

Phytosphingosine

Wellness

• BY PIVETAL •

SHAKE WELL BEFORE USE

6.8 FL. OZ. (200 mL)

NDC 46066-165-14

SUFFUSION

P +PS Mousse

Pramoxine HCl 1%, Phytosphingosine Salicyloyl 0.05%

Soothing Mousse FOR CATS & DOGS





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Rev. 07/19 P128CV



F41610F-US 18-L1-v2

SUFFUSION P PS MOUSSE

pramoxine hydrochloride, phytosphingosine salicyloyl liquid

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:46066-165
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
PRAMO XINE HYDRO CHLO RIDE (UNII: 88 AYB8 67L5) (PRAMO XINE - UNII: 068 X84E056)	PRAMO XINE HYDRO CHLO RIDE	10 mg in 1 mL			
SALICYLOYL PHYTOSPHINGOSINE (UNII: U891J4JCNH) (SALICYLOYL PHYTOSPHINGOSINE - UNII: U891J4JCNH)	SALICYLOYL PHYTOSPHINGOSINE	0.5 mg in 1 mL			

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
GLYCERIN (UNII: PDC6A3C0OX)		
PEG-8 DIMETHICONE (UNII: GIA7T764OD)		
SO DIUM LACTATE (UNII: TU7HW0 W0 QT)		
POLYSORBATE 80 (UNII: 6 OZP39 ZG8 H)		
POLOXAMER 184 (UNII: BIS92ZSF57)		
OAT (UNII: Z6J799EAJK)		
ALOE VERA LEAF (UNII: ZY81Z83H0X)		
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)		

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46066-165-14	200 mL in 1 BOTTLE, PLASTIC		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/11/2019	

Labeler - Aspen Veterinary Resource, LTD. (627265361)

Registrant - Ceva Sante Animale (261126049)

Revised: 10/2019 Aspen Veterinary Resource, LTD.