SUFFUSION P PS- pramoxine hydrochloride, phytosphingosine salicyloyl shampoo 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.

Suffusion P +PS Shampoo

ACTIVE INGREDIENTS: Pramoxine HCI 1%, Phytosphingosine Salicyloyl 0.05%.

INACTIVE INGREDIENTS: Water, Sodium C14-16 Olefin Sulfonate, Cocamidopropyl Betaine, Disodium Cocoamphodiacetate, Glycerin, Sodium Lactate, Hydroxypropyl Methylcellulose, Tetrasodium EDTA, Fragrance, Hydrolyzed Oat Protein, Carthamus Tinctorius (Safflower) Seed Oil, Citric Acid, Sodium Chloride, Methylchloroisothiazolinone, Methylisothiazolinone.

PROPERTIES: Suffusion P +PS Shampoo is formulated for the temporary relief of itching. This low-lather formula contains pramoxine HCl, a mild numbing agent, as well as colloidal oatmeal and essential fatty acids to further soothe irritated skin. Suffusion P +PS Shampoo also contains phytosphingosine, a pro-ceramide to help moisturize and support a healthy skin barrier.

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

DIRECTIONS FOR USE: Use 2-3 times per week until symptoms subside or as directed by your veterinarian. Wet the animal with cool water from the neck down and apply shampoo first on the skin abnormalities. Starting with a quarter-size amount of product, massage into the fur to reach the skin. Repeat until the entire body is lightly coated with shampoo. Leave shampoo on for 10 minutes before rinsing with cool water until the water runs clear. For a rinse-free solution between baths, ask your veterinarian about Suffusion P +PS Spray or Mousse.

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 - 8 OUNCE (237 mL) Bottle

NDC 46066-164-90

SUFFUSIONTM

P +PS Shampoo

Pramoxine HCl 1%, Phytosphingosine Salicyloyl 0.05%

Soothing Shampoo

FOR CATS & DOGS

Phytosphingosine

• BY PIVETAL •

8 FL. OZ. (237 mL)

NDC 46066-164-90

SUFFUSION[™]

P +PS Shampoo

Pramoxine HCl 1%, Phytosphingosine Salicyloyl 0.05%

Soothing Shampoo FOR CATS & DOGS





8 FL, OZ, (237 mL)

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Rev. 07/19 P126CV



F41710G-US 18-01-v

PRINCIPAL DISPLAY PANEL - 16 OUNCE (473 mL) Bottle

NDC 46066-164-91

SUFFUSIONTM

P +PS Shampoo

Pramoxine HCl 1%, Phytosphingosine Salicyloyl 0.05%

Soothing Shampoo

FOR CATS & DOGS

Phytosphingosine

Wellness

• BY PIVETAL •

16 FL. OZ. (473 mL)

NDC 46066-164-91

SUFFUSION

P +PS Shampoo

Pramoxine HCl 1%, Phytosphingosine Salicyloyl 0.05%

Soothing Shampoo FOR CATS & DOGS





16 FL, OZ, (473 mL)

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

Rev. 07/19 P127CV



F41730F-US 18-P1-v2

SUFFUSION P PS

pramoxine hydrochloride, phytosphingosine salicyloyl shampoo

Product Information

Product Type OTC ANIMAL DRUG Item Code (Source) NDC:46066-164

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PRAMO XINE HYDRO CHLO RIDE (UNII: 88 AYB867L5) (PRAMO XINE - UNII: 068 X84E056)	PRAMOXINE HYDROCHLORIDE	10 mg in 1 mL
SALICYLOYL PHYTOSPHINGOSINE (UNII: U891J4JCNH) (PHYTOSPHINGOSINE - UNII:GIN46U9Q2Q)	SALICYLOYL PHYTOSPHINGOSINE	0.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)	
COCAMIDO PRO PYL BETAINE (UNII: 50 CF3 O 11 KX)	
DISO DIUM CO CO AMPHO DIACETATE (UNII: 18L9 G3U51M)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM LACTATE (UNII: TU7HW0W0QT)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
EDETATE SO DIUM (UNII: MP1J8420 LU)	
SO DIUM CHLO RIDE (UNII: 451W47IQ8 X)	
CITRIC ACID MONO HYDRATE (UNII: 2968 PHW8 QP)	
OATMEAL (UNII: 8 PI54V663Y)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
METHYLCHLORO ISO THIAZO LINO NE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)	

	ackaging					
Ш	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
	NDC:46066-164-90	237 mL in 1 BOTTLE, PLASTIC				
	NDC:46066-164-91	473 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.