SUFFUSION P- pramoxine hydrochloride 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

FOR DOGS AND CATS

Pramoxine HCI 1%

ANTI-ITCH

SHAMPOO & CONDITIONER

ACTIVE INGREDIENTS: Pramoxine HCl 1%.

INACTIVE INGREDIENTS: Water, Sodium C14-16 Olefin Sulfonate, PEG-7 Glyceryl Cocoate, Sodium Chloride, Disodium Cocoamphodiacetate, Cocamidopropyl Betaine, Glycerin, Sodium Lactate, Avena Sativa (Oat) Kernal Extract, Ceramide EOP, Ceramide EOS, Ceramide NP, Carthamus Tinctorius (Safflower) Seed Oil, PEG-8, Laurate, Laureth-4, Fragrance, Citric Acid, Potassium Sorbate, Methylchloroisothiazolinone, Methylisothiazolinone.

PROPERTIES: Suffusion™ P Shampoo is a conditioning shampoo with pramoxine to help relieve itching. Skin nourishing nutrients moisturize and calm the skin. They also support the skin's natural immune system and provide building blocks for renewed skin barrier integrity.

INDICATIONS: For use on dogs or cats for the temporary relief of itching and skin irritations.

DIRECTIONS FOR USE: Bathe 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. Wash hands after use. For a rinse-free solution between baths, use Suffusion™ P Mousse or Suffusion HC Spray.

CAUTIONS: For external use on dogs and cats 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.

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.

PRINCIPAL DISPLAY PANEL - 8 OUNCE (237 mL) Bottle

Pivetal

NDC 46066-077-90

SUFFUSION™ P

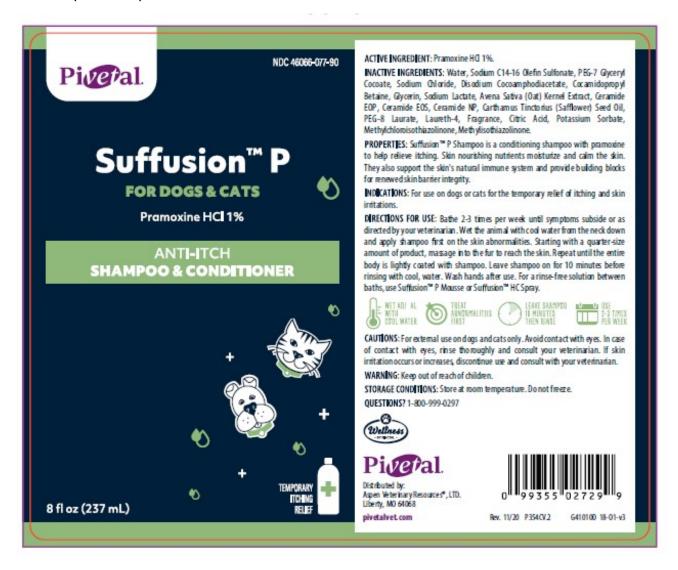
FOR CATS & DOGS

Pramoxine HCl 1%

ANTI-ITCH

SHAMPOO & CONDITIONER

8 fl oz (237 mL)



PRINCIPAL DISPLAY PANEL - 16 OUNCE (473 mL) Bottle

NDC 46066-077-91

SUFFUSION™ P

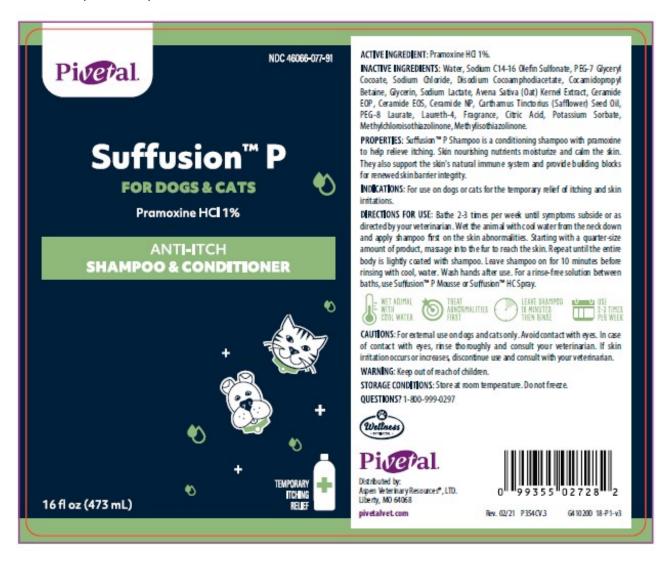
FOR CATS & DOGS

Pramoxine HCI 1%

ANTI-ITCH

SHAMPOO & CONDITIONER

16 fl oz (473 mL)



SUFFUSION P

pramoxine hydrochloride shampoo

Product Information			
Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:46066-077
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)		
SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)		
PEG-7 GLYCERYL COCOATE (UNII: VNX7251543)		
SODIUM CHLORIDE (UNII: 451W47IQ8X)		
DISODIUM COCOAMPHODIACETATE (UNII: 18L9G3U51M)		
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)		
GLYCERIN (UNII: PDC6A3C0OX)		
SODIUM LACTATE (UNII: TU7HW0W0QT)		
AVENANTHRAMIDES (UNII: 5PA41O4AIT)		
CERAMIDE 1 (UNII: 5THT33P7X7)		
CERAMIDE EOS (UNII: CR0J8RN66K)		
CERAMIDE NP (UNII: 4370DF050B)		
SAFFLOWER OIL (UNII: 65UEH262IS)		
PEG-8 LAURATE (UNII: 76208IWA10)		
LAURETH-4 (UNII: 6HQ855798J)		
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)		
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)		
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)		
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46066-077-90	237 mL in 1 BOTTLE, PLASTIC		
2	NDC:46066-077-91	473 mL in 1 BOTTLE, PLASTIC		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		04/02/2021		

Labeler - Aspen Veterinary Resource, LTD. (627265361)

Registrant - Ceva Sante Animale (261126049)

Revised: 4/2021 Aspen Veterinary Resource, LTD.