## SUFFUSION 4% PS- chlorhexidine gluconate, 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.

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#### **Suffusion 4% +PS SHAMPOO**

**ACTIVE INGREDIENTS:** Chlorhexidine Gluconate 4%, Phytosphingosine Salicyloyl 0.05%.

**INACTIVE INGREDIENTS:** Water, Lauramine Oxide, Cocamidopropyl Betaine, Polyacrylate-1 Crosspolymer, Disodium Oleamido MIPA Sulfosuccinate, Decyl Glucoside, Glycolic Acid, Tetrasodium EDTA, Fragrance, Methylchloroisothiazolinone, Methylisothiazolinone, FD&C Yellow #6.

**PROPERTIES:** Suffusion 4% +PS Shampoo is formulated with chlorhexidine gluconate, an antibacterial and antifungal agent for skin cleansing. This low-lather formula contains phytosphingosine, a pro-ceramide to help moisturize and support a healthy skin barrier.

**INDICATIONS:** For the management of bacterial or fungal skin infections in dogs and cats that are responsive to chlorhexidine gluconate.

**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 the shampoo on for 10 minutes before rinsing with cool water until the water runs clear.

**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<sup>®</sup>, LTD.

Liberty, MO 64068

www.pivetalvet.com

### PRINCIPAL DISPLAY PANEL - 8 OUNCE (237 mL) Bottle

NDC 46066-159-90

**SUFFUSION**<sup>TM</sup>

4% +PS Shampoo

Chlorhexidine Gluconate 4%,

Phytosphingosine Salicyloyl 0.05%

Antis eptic Shampoo

FOR CATS & DOGS

Phytosphingosine

Wellness

• BY PIVETAL •

8 FL. OZ. (237 mL)

NDC 46066-159-90

# **SUFFUSION**

### 4% +PS Shampoo

Chlorhexidine Gluconate 4%, Phytosphingosine Salicyloyl 0.05%

Antiseptic Shampoo FOR CATS & DOGS





8 FL. OZ. (237 mL)

ACTIVE INGREDIENTS: Chlorhexidine Gluconate 4%, Phytosphingosine Salicyloyl 0.05%.

INACTIVE INGREDIENTS: Water, Lauramine Oxide, Cocamidopropyl Betaine, Polyacrylate-1 Crosspolymer, Disodium Oleamido MIPA Sulfosuccinate, Decyl Glucoside, Glycolic Acid, Tetrasodium EDTA, Fragrance,

Methyl chloroisothiazolinone, Methylisothiazolinone, FD&C Yellow~#6.

PROPERTIES: Suffusion 4% +PS Shampoo is formulated with chlorhexidine gluconate, an antibacterial and antifungal agent for skin cleansing. This low-lather formula contains phytosphingosine, a pro-ceramide to help moisturize and support a healthy skin barrier.

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Rev. 07/19 P118CV



F38210F-US 18-01-v2

### PRINCIPAL DISPLAY PANEL - 16 OUNCE (473 mL) Bottle

NDC 46066-159-91

**SUFFUSION**<sup>TM</sup>

4% +PS Shampoo

Chlorhexidine Gluconate 4%,

Phytosphingosine Salicyloyl 0.05%

**Antiseptic Shampoo** 

FOR CATS & DOGS

Phytosphingosine

Wellness

16 FL. OZ. (473 mL)

NDC 46066-159-91

# **SUFFUSION**

## 4% +PS Shampoo

Chlorhexidine Gluconate 4%, Phytosphingosine Salicyloyl 0.05%

Antiseptic Shampoo FOR CATS & DOGS





16 FL OZ. (473 mL)

ACTIVE INGREDIENTS: Chlorhexidine Gluconate 4%, Phytosphingosine Salicyloyl 0.05%.

INACTIVE INGREDIENTS: Water, Lauramine Oxide, Cocamidopropyl Betaine, Polyacrylate-1 Crosspolymer, Disodium Oleamido MIPA Sulfosuccinate, Decyl Glucoside, Glycolic Acid, Tetrasodium EDTA, Fragrance,

Methylchloroisothiazolinone, Methylisothiazolinone, FD&C Yellow #6.

PROPERTIES: Suffusion 4% +PS Shampoo is formulated with chlorhexidine gluconate, an antibacterial and antifungal agent for skin cleansing. This low-lather formula contains phytosphingosine, a pro-ceramide to help moisturize and support a healthy skin barrier.

**INDICATIONS:** For the management of bacterial or fungal skin infections in dogs and cats that are responsive to chlorhexidine gluconate.

**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.

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QUESTIONS? 1-800-999-0297



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Rev. 07/19 P119CV



F38230F-US 18-P1-v2

#### **SUFFUSION 4% PS**

chlorhexidine gluconate, phytosphingosine salicyloyl shampoo

# Product Information Product Type OTC ANIMAL DRUG Item Code (Source) NDC:46066-159 Route of Administration TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
<b>CHLORHEXIDINE GLUCONATE</b> (UNII: MOR8 4 MUD8 E) (CHLORHEXIDINE - UNII: R4KO0 DY52L)	CHLORHEXIDINE GLUCONATE	40 mg in 1 mL		
SALICYLOYL PHYTOSPHINGOSINE (UNII: U891J4JCNH) (SALICYLOYL PHYTOSPHINGOSINE - UNII: U891J4JCNH)	SALICYLOYL PHYTOSPHINGOSINE	0.5 mg in 1 mL		

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
LAURAMINE O XIDE (UNII: 4F6 FC4MI8 W)	
COCAMIDO PRO PYL BETAINE (UNII: 50 CF30 11KX)	
DISODIUM OLEAMIDO MIPA-SULFOSUCCINATE (UNII: 0MBZ20845F)	
DECYL GLUCO SIDE (UNII: Z17H97EA6Y)	
GLYCOLIC ACID (UNII: 0 WT12SX38S)	
EDETATE SO DIUM (UNII: MP1J8420LU)	
METHYLCHLORO ISO THIAZO LINO NE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)	

Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
1 NDC:46066-159-90	237 mL in 1 BOTTLE, PLASTIC				
2 NDC:46066-159-91	473 mL in 1 BOTTLE, PLASTIC				

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
unapproved drug other		09/27/2019			

### **Labeler** - Aspen Veterinary Resource, Ltd. (627265361)

**Registrant -** Ceva Sante Animale (261126049)

Revised: 9/2019 Aspen Veterinary Resource, Ltd.