SUFFUSION EAR CLEANER- salicylic acid, phytosphingosine hcl solution 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 Ear Cleaner

ACTIVE INGREDIENTS: Salicylic Acid 0.15%, Phytosphingosine HCl 0.01%.

INACTIVE INGREDIENTS: Water, SDA 40B 190 Proof, Propylene Glycol, Disodium Oleamido MIPA Sulfosuccinate, Glycerin, Nonoxynol-12, Benzoic Acid, Benzyl Alcohol, Lactic Acid, Tetrasodium EDTA, Sodium Dioctyl Sulfosuccinate, Aloe Barbadensis Leaf Juice, Fragrance.

PROPERTIES: Suffusion Ear Cleaner gently cleans, deodorizes and dries the ear canal to help maintain healthy ears. It contains aloe vera to moisturize, and phytosphingosine, a pro-ceramide, to help support a healthy skin barrier.

INDICATION: For cleansing and/or drying the ear canal in dogs and cats.

DIRECTIONS FOR USE: Ask your veterinarian which of the two following protocols is best for your pet:

- 1) Moisten a cotton ball with solution and place at the entrance of the ear canal; OR
- 2) Hold ear flap upward and fill with solution.

Then gently massage the base of the ear for 60 seconds. Remove cotton ball (if used) and allow pet to shake its head. Gently wipe away visible debris and exceess solution with a clean cotton ball.

CAUTIONS: For external use on dogs and cats only. Avoid contact with the eyes. If eye contact occurs, rinse thoroughly and consult your veterinarian. If skin irritation occurs or increases, discontinue use and consult with your veterinarian. Do not use with a suspected ruptured eardrum. 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 - 4 OUNCE (118 mL) Bottle

NDC 46066-168-80

SUFFUSIONTM

Ear Cleaner

Salicylic Acid 0.15%,

Phytosphingosine HCl 0.01%

Cleansing/Drying Solution

FOR CATS & DOGS

Phytosphingosine

Wellness

- PIVETAL •
- 4 FL. OZ. (118 mL)

ACTIVE INGREDIENTS: Salicylic Acid 0.15%. Phytosphingosine HCI 0.01%.

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www.pivetalvet.com Rev. 07/19 P134CV

F41410H-US 18-V1-v2

NDC 46066-168-80

SUFFUSION"

Ear Cleaner

Salicylic Acid 0.15%, Phytosphingosine HCI 0.01%

Cleansing/Drying Solution **FOR CATS & DOGS**



4 FL. OZ. (118 mL)

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QUESTIONS? 1-800-999-0297



PRINCIPAL DISPLAY PANEL - 8 OUNCE (237 mL) Bottle

NDC 46066-168-90

SUFFUSIONTM

Ear Cleaner

Salicylic Acid 0.15%,

Phytosphingosine HCl 0.01%

Cleansing/Drying Solution

FOR CATS & DOGS

Phytosphingosine

Wellness

• PIVETAL •

8 FL. OZ. (237 mL)

NDC 46066-168-90

SUFFUSION

Ear Cleaner

Salicylic Acid 0.15%, Phytosphingosine HCl 0.01%

Cleansing/Drying Solution FOR CATS & DOGS





8 FL, OZ, (237 mL)

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QUESTIONS? 1-800-999-0297



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Rev. 07/19 P135CV



F41420I-US 18-01-v2

PRINCIPAL DISPLAY PANEL - 16 OUNCE (473 mL) Bottle

NDC 46066-168-91

SUFFUSIONTM

Ear Cleaner

Salicylic Acid 0.15%,

Phytosphingosine HCl 0.01%

Cleansing/Drying Solution

FOR CATS & DOGS

Phytosphingosine

Wellness

• PIVETAL •

16 FL. OZ. (473 mL)

NDC 46066-168-91

SUFFUSION[™]

Ear Cleaner

Salicylic Acid 0.15%, Phytosphingosine HCl 0.01%

Cleansing/Drying Solution FOR CATS & DOGS





16 FL, OZ, (473 mL)

ACTIVE INGREDIENTS: Salicylic Acid 0.15%, Phytosphingosine HCI 0.01%.

INACTIVE INGREDIENTS: Water, SDA 40B 190 Proof, Propylene Glycol, Disodium Oleamido MIPA Sulfosuccinate, Glycerin, Nonoxynol-12, Benzoic Acid, Benzyl Alcohol, Lactic Acid, Tetrasodium EDTA, Sodium Dioctyl Sulfosuccinate, Aloe Barbadensis Leaf Juice, Fragrance.

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QUESTIONS? 1-800-999-0297



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Rev. 07/19 P136CV



F41440H-US 18-P1-v2

SUFFUSION EAR CLEANER

salicylic acid, phytosphingosine hcl solution

Product Information

I	Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:46066-168

Route of Administration TOPICAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ) PHYTOSPHINGOSINE HYDROCHLORIDE (UNII: TT871XV7TU) PHYTOSPHINGOSINE - UNII:GIN46 U9 Q2Q) PHYDROCHLORIDE in 1 mL

Inactive Ingredients	
Ingredient Name	Strength

WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DISODIUM OLEAMIDO MIPA-SULFOSUCCINATE (UNII: 0 MBZ20845F)	
NONOXYNOL-12 (UNII: 6NR43D77O6)	
GLYCERIN (UNII: PDC6A3C0OX)	
BENZOIC ACID (UNII: 8 SKN0 B0 MIM)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
LACTIC ACID (UNII: 33X04XA5AT)	
EDETATE SO DIUM (UNII: MP1J8420 LU)	
DI-N-O CTYL SO DIUM SULFO SUCCINATE (UNII: 4YLY5570 Y0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:46066-168-80	118 mL in 1 BOTTLE, PLASTIC			
2	NDC:46066-168-90	237 mL in 1 BOTTLE, PLASTIC			
3	NDC:46066-168-91	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: 2/2020 Aspen Veterinary Resource, LTD.