

SUFFUSION SA EAR CLEANER- salicylic acid 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™ SA

FOR DOGS & CATS

EAR CLEANER

ACTIVE INGREDIENTS: Salicylic Acid 0.15%.

INACTIVE INGREDIENTS: Water, SD Alcohol 40-B, Propylene Glycol, Glycerin, Benzoic Acid, Benzyl Alcohol, Disodium Oleamido MIPA Sulfosuccinate, Nonoxynol-12, Diethylhexyl Sodium Sulfosuccinate, Lactic Acid, Aloe Barbadensis (Aloe Vera) Leaf Juice, Avena Sativa (Oat) Kernel Oil, Ceramide EOP, Ceramide EOS, Ceramide NP, Fragrance, Potassium Sorbate, Tetrasodium EDTA.

PROPERTIES: Suffusion™ SA Ear Cleaner cleans, dries, and deodorizes the ear canal. Contains salicylic acid, a beta-hydroxy acid (BHA) to exfoliate and penetrate dead skin cells, wax build-up and dirt. 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 to cleanse, deodorize and dry the ear canal.

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 excess solution with a clean cotton ball. Wash hands after use.

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. Do not use with a suspected ruptured eardrum.

WARNING: Keep out of reach of children.

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

QUESTIONS? 1-800-999-0297

Pivotal

Distributed by:

Aspen Veterinary Resources®, LTD.

Liberty, MO 64068

pivetalvet.com

PRINCIPAL DISPLAY PANEL - 4 OUNCE (118 mL) Bottle

Pivetal®

NDC 46066-078-88

Suffusion™ SA

FOR DOGS & CATS

Salicylic Acid 0.15%,

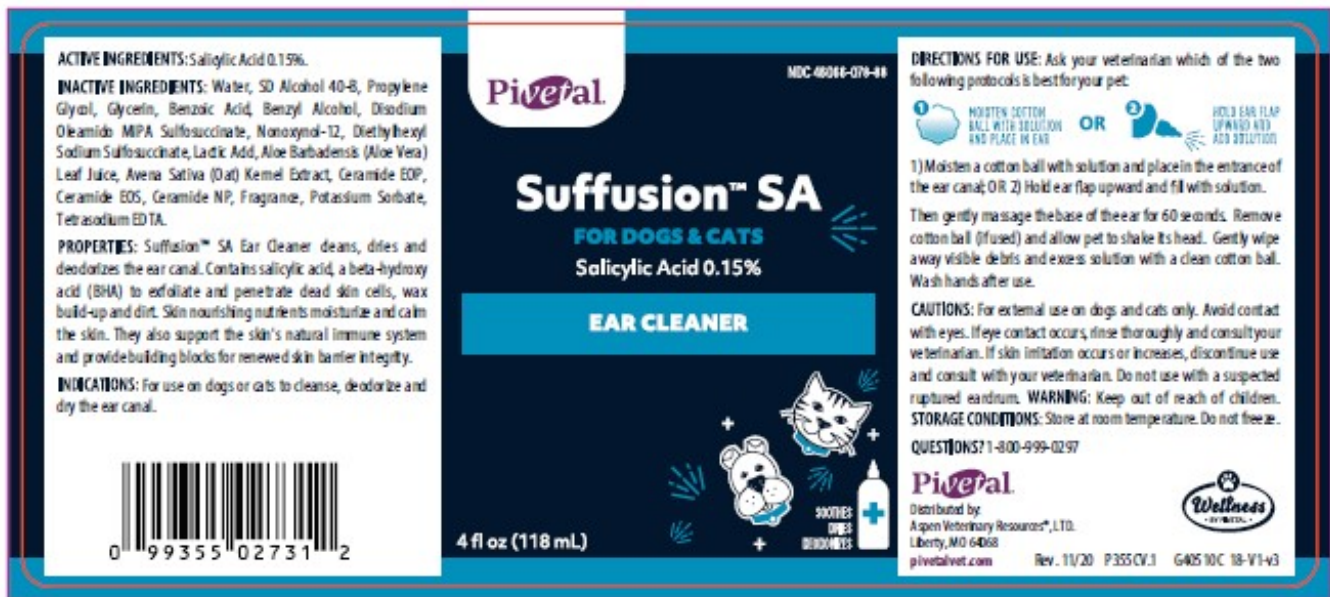
EAR CLEANER

SOOTHES

DRIES

DEODORIZES

4 fl oz (118 mL)



PRINCIPAL DISPLAY PANEL - 8 OUNCE (237 mL) Bottle

Pivetal®

NDC 46066-078-90

Suffusion™ SA

FOR DOGS & CATS

Salicylic Acid 0.15%,

EAR CLEANER

SOOTHES

DRIES

DEODORIZES

8 fl oz (237 mL)

PRINCIPAL DISPLAY PANEL - 16 OUNCE (473 mL) Bottle

Pivotal®

NDC 46066-078-91

Suffusion™ SA

FOR DOGS & CATS

Salicylic Acid 0.15%,

EAR CLEANER

SOOTHES

DRIES

DEODORIZES

16 fl oz (473 mL)

Pivotal NDC 46066-078-91

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Salicylic Acid 0.15%

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INDICATIONS: For use on dogs or cats to cleanse, deodorize and dry the ear canal.

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

1) MOISTEN COTTON BALL WITH SOLUTION AND PLACE IN EAR OR 2) HOLD EAR FLAP UPWARD AND ADD SOLUTION

1) Moisten a cotton ball with solution and place in 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 excess solution with a clean cotton ball. Wash hands after use.

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Wellness
BY PIVOTAL

Pivotal

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

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Rev. 11/20 P353CV.3 G40530C 18-P1-v3

SUFFUSION SA EAR CLEANER

salicylic acid solution

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:46066-078
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: 0414PZ4LPZ) (SALICYLIC ACID - UNII:0414PZ4LPZ)	SALICYLIC ACID	1.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
GLYCERIN (UNII: PDC6A3C0OX)
BENZOIC ACID (UNII: 8SKN0B0MIM)
BENZYL ALCOHOL (UNII: LKG8494WBH)
DISODIUM OLEAMIDO MIPA-SULFOSUCCINATE (UNII: 0MBZ20845F)
NONOXYNOL-12 (UNII: 6NR43D77O6)
DOCUSATE SODIUM (UNII: F05Q2T2JA0)
LACTIC ACID (UNII: 33X04XA5AT)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
AVENANTHRAMIDES (UNII: 5PA41O4AIT)
CERAMIDE 1 (UNII: 5THT33P7X7)
CERAMIDE EOS (UNII: CROJ8RN66K)
CERAMIDE NP (UNII: 4370DF050B)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
EDETATE SODIUM (UNII: MP1J8420LU)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46066-078-88	118 mL in 1 BOTTLE, PLASTIC		
2	NDC:46066-078-90	237 mL in 1 BOTTLE, PLASTIC		
3	NDC:46066-078-91	473 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/30/2021	

Labeler - Aspen Veterinary Resource, LTD. (627265361)

Registrant - Ceva Sante Animale (261126049)

Revised: 5/2021

Aspen Veterinary Resource, LTD.