

CERASOOTHE SA EAR CLEANER- salicylic acid solution
Butler Animal Health Supply, LLC dba Covetrus North America

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.

CeraSoothe SA
Otic Cleansing Solution

Fragrance: Cucumber melon

Formulated for cats, dogs, and horses

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. Ceramides and avenanthramides are skin nourishing nutrients that moisturize and calm the skin. They also support the skin's natural immune system and provide building blocks for renewed skin barrier integrity.

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.

Indications: For use on cats, dogs, and horses 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 cats, dogs, and horses 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.

Storage: Store at room temperature. Do not freeze.

Questions?

(855) 724-3461

Distributed by:

Covetrus North America

400 Metro Place North

Dublin, OH 43017

covetrus.com

PRINCIPAL DISPLAY PANEL - 237 mL Bottle Label

Inspired by veterinarians

CeraSoothe™
SA

Otic Cleansing Solution
Fragrance: Cucumber melon

Salicylic acid 0.15%

Formulated for cats, dogs, and horses

Keep out of reach of children
For animal use only

NDC: 11695-6989-1
Net contents: 8 fl oz (237mL)

covetrus

Inspired by veterinarians



Otic Cleansing Solution

Fragrance: Cucumber melon

Salicylic acid 0.15%



Formulated for cats, dogs, and horses

Keep out of reach of children
For animal use only

NDC: 11695-6989-1

Net contents: 8 fl oz (237mL)



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Storage: Store at room temperature. Do not freeze.

Reorder #073124

Questions?
(855) 724-3461

AH-073124-02
REV: 0621

Distributed by:
Covetrus North America
400 Metro Place North
Dublin, OH 43017
covetrus.com



G40520E-US 18-01-v4

(01)00840066511108

PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label

Inspired by veterinarians

CeraSoothe™
SA

Otic Cleansing Solution
Fragrance: Cucumber melon

Salicylic acid 0.15%

Formulated for cats, dogs, and horses

Keep out of reach of children
For animal use only

NDC: 11695-6989-2
Net contents: 16 fl oz (473mL)

covetrus

Inspired by veterinarians



Otic Cleansing Solution

Fragrance: Cucumber melon

Salicylic acid 0.15%



Formulated for cats, dogs, and horses

Keep out of reach of children
For animal use only

NDC: 11695-6989-2

Net contents: 16 fl oz (473mL)



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Storage: Store at room temperature. Do not freeze.

Reorder #073123

Questions?
(855) 724-3461
AH-073123-02
REV: 0621

Distributed by:
Covetrus North America
400 Metro Place North
Dublin, OH 43017
covetrus.com



G40530E-US 18-P1-v4

CERASOOTHE SA EAR CLEANER

salicylic acid solution

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:11695-6989
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, UNSPECIFIED FORM (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:11695-6989-1	237 mL in 1 BOTTLE, PLASTIC		
2	NDC:11695-6989-2	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 - Butler Animal Health Supply, LLC dba Covetrus North America (603750329)

Registrant - Ceva Sante Animale (261126049)