

**MICELLAR OTIC CLEANSER- phytosphingosine salicyloyl 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.*

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**MICELLAR OTIC CLEANSER**

**Micellar Otic Cleanser**

**Phytosphingosine Salicyloyl 0.05%**

A non-greasy formula that cleans and deodorizes the ear canal. Contains micellar technology to help emulsify and wash out waxy debris without drying the skin. It also contains phytosphingosine, a pro-ceramide to help support a healthy skin barrier.

**Active Ingredient:** Phytosphingosine Salicyloyl 0.05%

**Inactive Ingredients:** Water, polysorbate 80, SD alcohol 40-B, propylene glycol, laureth-9, poloxamer 184, imidazolidinyl urea, phenoxyethanol, potassium sorbate, biosaccharide gum-2, citric acid, fragrance.

**Indications:** For use in cats, dogs, and horses to gently cleanse the ear canal or other areas of the skin.

**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 in the entrance of the ear canal; OR
- 2) Hold the 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 eyes. If eye contact occurs, rinse thoroughly and consult with 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.

**Reorder #073122**

**Questions?** (855) 724-3461

**Distributed by:**

Covetrus North America

400 Metro Place North

Dublin, OH 43017

**covetrus.com**

## PRINCIPAL DISPLAY PANEL - 125 mL BOTTLE

**Micellar**

**Otic Cleanser**

**Fragrance: Green tea**

Phytosphingosine salicyloyl 0.05%

Formulated for cats, dogs, and horses

**Keep out of reach of children**

For animal use only

NDC: 11695-6988-1

**Net contents: 4.2 fl oz (125mL)**

**covetrus**

Inspired by veterinarians

# Micellar

**Otic Cleanser**

**Fragrance: Green tea**

Phytosphingosine salicyloyl 0.05%



Formulated for cats, dogs, and horses

**Keep out of reach of children**

For animal use only

NDC: 11695-6988-1

**Net contents: 4.2 fl oz (125mL)**

**covetrus**

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**Storage:** Store at room temperature. Do not freeze.

**Reorder #073121**

**Questions?**  
(855) 724-3461  
AH-073121-01  
REV: 1220

**Distributed by:**

Covetrus North America  
400 Metro Place North  
Dublin, OH 43017  
**covetrus.com**



G39310E 01-R1-v5

(01)00840066511078

## PRINCIPAL DISPLAY PANEL - 250 mL BOTTLE

**Micellar**

## Otic Cleanser

### Fragrance: Green tea

Phytosphingosine salicyloyl 0.05%

Formulated for cats, dogs, and horses

### Keep out of reach of children

For animal use only

NDC: 11695-6988-2

**Net contents: 8.4 fl oz (250mL)**

**covetrus**

Inspired by veterinarians

# Micellar

Otic Cleanser

Fragrance: Green tea

Phytosphingosine salicyloyl 0.05%



Formulated for cats, dogs, and horses

Keep out of reach of children

For animal use only

NDC: 11695-6988-2

Net contents: 8.4 fl oz (250mL)

**covetrus**

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**Storage:** Store at room temperature. Do not freeze.

Reorder #073122

Questions?  
(855) 724-3461  
AH-073122-01  
REV: 1220

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400 Metro Place North  
Dublin, OH 43017  
**covetrus.com**



639320D 01-T1-v5

**MICELLAR OTIC CLEANSER**

phytosphingosine salicyloyl solution

### Product Information

<b>Product Type</b>	OTC ANIMAL DRUG	<b>Item Code (Source)</b>	NDC:11695-6988
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SALICYLOYL PHYTOSPHINGOSINE</b> (UNII: U891J4JCNH) (PHYTOSPHINGOSINE - UNII:GIN46U9Q2Q)	SALICYLOYL PHYTOSPHINGOSINE	.5 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>LAURETH-9 PHOSPHATE</b> (UNII: 0N8G76HI1O)	
<b>POLOXAMER 184</b> (UNII: BIS92ZSF57)	
<b>BIOSACCHARIDE GUM-2</b> (UNII: UVQ34I5XKQ)	
<b>IMIDUREA</b> (UNII: M629807ATL)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11695-6988-1	125 mL in 1 BOTTLE, PLASTIC		
2	NDC:11695-6988-2	250 mL in 1 BOTTLE, PLASTIC		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/16/2021	

**Labeler** - Butler Animal Health Supply, LLC dba Covetrus North America (603750329)

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