

PHYTO MICELLAR OTIC CLEANSER- phytosphingosine hydrochloride 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](#).

Phyto micellar Otic Cleanser

Active ingredient: Phytosphingosine HCl 0.02%

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.

Properties: Phyto micellar otic cleansing solution contains micellar technology and soothing agents to help emulsify and wash out waxy debris without drying the skin. The solution is also non-greasy and non-staining. It also contains phytosphingosine, a pro-ceramide to help support a healthy skin barrier.

Indications: For use in dogs and cats only. Ideal for cleaning the ear canal, eye contours, and skin folds. May also be used to clean soiled and matted hair, or greasy skin associated with seborrheic conditions.

Directions for use: Shake well before use. For ear cleaning, 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 upwards and fill the ear canal with solution.

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

To clean other areas of the skin, moisten a cotton ball or gauze with the solution and gently wipe the area to cleanse and remove debris. Repeat as necessary until clean.

Cautions: For external use in dogs and cats 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 in the case of a suspected ruptured eardrum.

Storage conditions: 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 - 125 mL BOTTLE

covetrus

NDC: 11695-7239-4

Phyto micellar

Phytosphingosine HCl 0.02%

Otic Cleansing Solution

For use on dogs and cats

For animal use only

Keep out of reach of children

Net contents: 4.2 fl oz (125 mL)



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Cautions: For external use on dogs and cats 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 in the case of a suspected ruptured eardrum.

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

Reorder #057870

Questions?

(855) 724-3461

AH-057870-02

REV: 0819

Distributed by:

Covetrus North America

400 Metro Place North

Dublin, OH 43017

covetrus.com



F04810V-US 01-R1-v3

PRINCIPAL DISPLAY PANEL - 250 mL BOTTLE

covetrus

NDC: 11695-7239-8

Phyto micellar

Phytosphingosine HCl 0.02%

Otic Cleansing Solution

For use on dogs and cats

For animal use only

Keep out of reach of children

Net contents: 8.4 fl oz (250 mL)



NDC: 11695-7239-8

Phyto micellar

Phytosphingosine HCl 0.02%

Otic Cleansing Solution

For use on dogs and cats

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Keep out of reach of children

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

Reorder #057871

Questions?

(855) 724-3461

AH-057871-02

REV: 0819

Distributed by:

Covetrus North America

400 Metro Place North

Dublin, OH 43017

covetrus.com



F04820E-US 01-T1-v3

PHYTO MICELLAR OTIC CLEANSER

phytosphingosine hydrochloride solution

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:11695-7239
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHYTOSPHINGOSINE HYDROCHLORIDE (UNII: TT871XV7TU) (PHYTOSPHINGOSINE - UNII:GIN46U9Q2Q)	PHYTOSPHINGOSINE HYDROCHLORIDE	0.2 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SEC-LAURETH-9 (UNII: 441JX1IO3Z)	
POLOXAMER 184 (UNII: BIS92ZSF57)	
BIO SACCCHARIDE GUM-2 (UNII: UVQ34I5XKQ)	
IMIDUREA (UNII: M629807ATL)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11695-7239-4	125 mL in 1 BOTTLE, PLASTIC		
2	NDC:11695-7239-8	250 mL in 1 BOTTLE, PLASTIC		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/01/2020	

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

Registrant - Ceva Sante Animale (261126049)

Revised: 12/2019

Butler Animal Health Supply, LLC dba Covetrus North America