

PHYTO S OTIC CLEANSING- salicylic acid, phytosphingosine hcl 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 S Otic Cleansing Solution

Active ingredients: Salicylic acid, 0.15%, phytosphingosine HCl 0.01%.

Inactive ingredients: Water, SDA 40B 190 proof, propylene glycol, disodium oleamido MIPA sulfosuccinate, nonoxynol-12, glycerin, fragrance, benzoic acid, benzyl alcohol, lactic acid, tetrasodium EDTA, sodium dioctyl sulfosuccinate, aloe barbadensis leaf juice.

Properties: Phyto S otic cleansing solution is formulated with salicylic acid, a beta-hydroxy acid (BHA) to exfoliate and penetrate dead skin cells and dirt to clean and deodorize the ear canal. It also contains phytosphingosine, a pro-ceramide to help moisturize and support a healthy skin barrier.

Indications: For use on dogs, cats, and horses only. For cleansing and/or drying the ear canal.

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 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.

Cautions: For external use in dogs, cats, and horses 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. Wash hands after use.

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 - 4 fl oz (118 mL)

covetrus

NDC: 11695-7223-4

Phyto S

Salicylic acid 0.15%,

phytosphingosine HCl 0.01%

Otic Cleansing Solution

For cleansing and/or drying the ear canal in dogs, cats and horses

For animal use only

Keep out of reach of children

Net contents: 4 fl oz (118 mL)

covetrus

NDC: 11695-7223-4

Phyto S

Salicylic acid 0.15%,
phytosphingosine HCl 0.01%


Otic Cleansing Solution

For cleansing and/or drying the ear canal in dogs, cats, and horses

For animal use only
Keep out of reach of children

Net contents: 4 fl oz (118 mL)

Active ingredients: Salicylic acid 0.15%, phytosphingosine HCl 0.01%.
Inactive ingredients: Water, SDA 40B 190 proof, propylene glycol, disodium oleamido MIPA sulfosuccinate, nonoxynol-12, glycerin, fragrance, benzoic acid, benzyl alcohol, lactic acid, tetrasodium EDTA, sodium dioctyl sulfosuccinate, aloe barbadensis leaf juice.
Properties: Phyto S otic cleansing solution is formulated with salicylic acid, a beta-hydroxy acid (BHA) to exfoliate and penetrate dead skin cells and dirt to clean and deodorize the ear canal. It also contains phytosphingosine, a pro-ceramide to help moisturize and support a healthy skin barrier.
Indications: For use on dogs, cats, and horses only. For cleansing and/or drying the ear canal.


F41410F-US 18-V1-v2

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 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.
Cautions: For external use on dogs, cats, and horses only. Avoid contact with the eyes. In case of contact with eyes, 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.
Storage: Store at room temperature. Do not freeze.

Reorder #038186
Questions?
(855) 724-3461
AH-038186-02 | REV: 0919

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

PRINCIPAL DISPLAY PANEL - 8 fl oz (237 mL)

covetrus

NDC: 11695-7223-8

Phyto S

Salicylic acid 0.15%,

phytosphingosine HCl 0.01%

Otic Cleansing Solution

For cleansing and/or drying the ear canal in dogs, cats and horses

For animal use only

Keep out of reach of children

Net contents: 8 fl oz (237 mL)

NDC: 11695-7223-8

Phyto S

Salicylic acid 0.15%,
phytosphingosine HCl 0.01%

Otic Cleansing Solution

For cleansing and/or drying the ear canal
in dogs, cats, and horses

For animal use only
Keep out of reach of children

Net contents: 8 fl oz (237 mL)

Active ingredients: Salicylic acid 0.15%, phytosphingosine HCl 0.01%.

Inactive ingredients: Water, SDA 40B 190 proof, propylene glycol, disodium oleamido MIPA sulfosuccinate, nonoxynol-12, glycerin, fragrance, benzoic acid, benzyl alcohol, lactic acid, tetrasodium EDTA, sodium dioctyl sulfosuccinate, aloe barbadensis leaf juice.

Properties: Phyto S otic cleansing solution is formulated with salicylic acid, a beta-hydroxy acid (BHA) to exfoliate and penetrate dead skin cells and dirt to clean and deodorize the ear canal. It also contains phytosphingosine, a pro-ceramide to help moisturize and support a healthy skin barrier.

Indications: For use on dogs, cats, and horses only. For cleansing and/or drying the ear canal.

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 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.

Cautions: For external use in dogs, cats, and horses 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. Wash hands after use.

Storage: Store at room temperature. Do not freeze.

Reorder #038187

Questions? (855) 724-3461

AH-038187-02

REV: 0919

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



F41420F-US 18-01-v2

PRINCIPAL DISPLAY PANEL - 16 ounce (473 mL)

covetrus

NDC: 11695-7223-6

Phyto S

Salicylic acid 0.15%,
phytosphingosine HCl 0.01%

Otic Cleansing Solution

For cleansing and/or drying the ear canal in dogs, cats and horses

For animal use only

Keep out of reach of children

Net contents: 16 fl oz (473 mL)

NDC: 11695-7223-6

Phyto S

Salicylic acid 0.15%,
phytosphingosine HCl 0.01%

Otic Cleansing Solution

For cleansing and/or drying the ear canal
in dogs, cats, and horses

For animal use only
Keep out of reach of children

Net contents: 16 fl oz (473 mL)

Active ingredients: Salicylic acid 0.15%, phytosphingosine HCl 0.01%.

Inactive ingredients: Water, SDA 40B 190 proof, propylene glycol, disodium oleamido MIPA sulfosuccinate, nonoxynol-12, glycerin, fragrance, benzoic acid, benzyl alcohol, lactic acid, tetrasodium EDTA, sodium dioctyl sulfosuccinate, aloe barbadensis leaf juice.

Properties: Phyto S otic cleansing solution is formulated with salicylic acid, a beta-hydroxy acid (BHA) to exfoliate and penetrate dead skin cells and dirt to clean and deodorize the ear canal. It also contains phytosphingosine, a pro-ceramide to help moisturize and support a healthy skin barrier.

Indications: For use on dogs, cats, and horses only. For cleansing and/or drying the ear canal.

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 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.

Cautions: For external use in dogs, cats, and horses 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. Wash hands after use.

Storage: Store at room temperature. Do not freeze.

Reorder #038315

Questions? (855) 724-3461

AH-038315-02

REV: 0919

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



F41440F-US 18-P1-v2

PHYTO S OTIC CLEANSING

salicylic acid, phytosphingosine hcl solution

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:11695-7223
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	1.5 mg in 1 mL
PHYTOSPHINGOSINE HYDROCHLORIDE (UNII: TT871XV7TU) (PHYTOSPHINGOSINE - UNII:GIN46U9Q2Q)	PHYTOSPHINGOSINE HYDROCHLORIDE	0.1 mg in 1 mL

Inactive Ingredients

Ingredient Name		Strength		
WATER (UNII: 059QF0KO0R)				
ALCOHOL (UNII: 3K9958V90M)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
DISODIUM OLEAMIDO MIPA-SULFOSUCCINATE (UNII: 0MBZ20845F)				
NONOXYNOL-12 (UNII: 6NR43D77O6)				
GLYCERIN (UNII: PDC6A3C0OX)				
BENZOIC ACID (UNII: 8SKN0B0MIM)				
BENZYL ALCOHOL (UNII: LKG8494WBH)				
LACTIC ACID (UNII: 33X04XA5AT)				
EDETATE SODIUM (UNII: MP1J8420LU)				
DI-N-OCTYL SODIUM SULFOSUCCINATE (UNII: 4YLY5570Y0)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11695-7223-4	118 mL in 1 BOTTLE, PLASTIC		
2	NDC:11695-7223-8	237 mL in 1 BOTTLE, PLASTIC		
3	NDC:11695-7223-6	473 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)