PHYTO EFA- phytosphingosine salicyloyl shampoo 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 EFA Moisturizing Shampoo

Active ingredients: Phytosphingosine salicyloyl 0.02%.

Inactive ingredients: Water, sodium C14-16 olefin sulfonate, cocamidopropyl betaine, sodium chloride, sodium lactate, fragrance, glycerin, disodium cocoamphodiacetate, propylene glycol, hydroxypropyl methylcellulose, citric acid, tetrasodium EDTA, carthamus tinctorius (safflower) seed oil, methylchloroisothiazolinone, methylisothiazolinone.

Properties: Phyto EFA moisturizing shampoo is for grooming and moisturizing dry or sensitive skin. Emollients and fatty acids hydrate and soothe the skin and help control dryness and irritations. This low-lather shampoo also contains phytosphingosine, a pro-ceramide to help support a healthy skin barrier.

Indications: For the management of dry, irritated, or sensitive skin.

Directions for use: Bathe as needed or as directed by your veterinarian. Wet the animal with lukewarm water from the neck down and apply shampoo. Starting with a quarter-size amount of product, massage into the fur to reach the skin. Repeat until the entire body is lightly coated with shampoo. Rinse with lukewarm water. For a rinse-free treatment between baths, ask your veterinarian about Phyto EFA moisturizing mousse.

Cautions: For external use on 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. 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 - 8 fl oz (237 mL)

covetrus

NDC: 11695-7230-8

Phyto EFA Shampoo

Phytosphingosine salicyloyl 0.02%

Moisturizing Shampoo

Moisturizing shampoo for dogs, cats and horses

For animal use only

Keep out of reach of children

Net contents: 8 fl oz (237 mL)



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Storage: Store at room temperature. Do not freeze.

Reorder #043469

Questions? (855) 724-3461

AH-043469-02 REV: 0719



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

F40610E-US 18-01-v2

PRINCIPAL DISPLAY PANEL - 16 fl oz (473 mL)

covetrus

NDC: 11695-7230-8

Phyto EFA Shampoo

Phytosphingosine salicyloyl 0.02%

Moisturizing Shampoo

Moisturizing shampoo for dogs, cats and horses

For animal use only

Keep out of reach of children

Net contents: 16 fl oz (473 mL)



NDC: 11695-7230-6

Phyto EFA

Phytosphingosine salicyloyl 0.02%

Moisturizing Shampoo

Moisturizing shampoo for dogs, cats, and horses

For animal use only Keep out of reach of children

Net contents: 16 fl oz (473 mL)

Active ingredients: Phytosphingosine salicyloyl 0.02%.

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Storage: Store at room temperature. Do not freeze.

Reorder #043470

Questions? (855) 724-3461

AH-043470-02 REV: 0719



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

F40630E-US 18-P1-v2

PRINCIPAL DISPLAY PANEL - 1 GALLON (3.785 L)

covetrus

NDC: 11695-7230-1

Phyto EFA Shampoo

Phytosphingosine salicyloyl 0.02%

Moisturizing Shampoo

Moisturizing shampoo for dogs, cats and horses

For animal use only

Keep out of reach of children

Net contents: 1 gallon (3.785 L)



NDC: 11695-7230-1

Phyto EFA

Phytosphingosine salicyloyl 0.02%

Moisturizing Shampoo

Moisturizing shampoo for dogs, cats, and horses

For animal use only **Keep out of reach of children**

Net contents: 1 gallon (3.785 L)

Active ingredients: Phytosphingosine salicyloyl 0.02%.

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Storage: Store at room temperature. Do not freeze.

Reorder #043471

Questions? (855) 724-3461

AH-043471-02 REV: 0719 Distributed by: Covetrus North America 400 Metro Place North Dublin, OH 43017 covetrus.com



F40620E-US 18-Q1-v2

PHYTO EFA

phytosphingosine salicyloyl shampoo

Product Information

Product TypeOTC ANIMAL DRUGItem Code (Source)NDC:11695-7230

Route of Administration TOPICAL

Active Ingredient/Active Moiety

8				
Ingredient Name	Basis of Strength	Strength		
SALICYLOYL PHYTOSPHINGOSINE (UNII: U891J4JCNH) (SALICYLOYL PHYTOSPHINGOSINE - UNII: U891J4JCNH)	SALICYLOYL PHYTOSPHINGOSINE	0.2 mg in 1 mL		

Inactive Ingredients Ingredient Name Strength WATER (UNII: 059QF0KO0R) SODIUM C14-16 OLEFIN SULFONATE (UNII: 09W3D3YF5U) COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX) DISODIUM COCOAMPHODIACETATE (UNII: 18L9G3U51M) SODIUM LACTATE (UNII: TU7HW0W0QT) GLYCERIN (UNII: PDC6A3C0OX)

PROPYLENE GLYCOL (UNII: 6 DC9 Q167V3)	
HYPROMELLOSES (UNII: 3NXW29 V3WO)	
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
CITRIC ACID MONO HYDRATE (UNII: 2968 PHW8 QP)	
METHYLCHLORO ISO THIAZO LINO NE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)	

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:11695-7230-8	237 mL in 1 BOTTLE, PLASTIC				
2	NDC:11695-7230-6	473 mL in 1 BOTTLE, PLASTIC				
3	NDC:11695-7230-1	3785 mL in 1 JUG				

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
unapproved drug other		0 1/0 1/20 20			

$\pmb{Labeler-} \textbf{Butler Animal Health Supply, LLC dba Covetrus North America (603750329)}$

Registrant - Ceva Sante Animale (261126049)

Revised: 12/2019 Butler Animal Health Supply, LLC dba Covetrus North America