#### PHYTO P ANTI-ITCH- pramoxine hydrochloride, 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.

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#### Phyto P Anti-itch Shampoo

**Active Ingredients:** Pramoxine HCI 1%, phytosphingosine salicyloyl 0.05%.

**Inactive Ingredients:** water, sodium C14-16 olefin sulfonate, cocamidopropyl betaine, disodium cocoamphodiacetate, glycerin, sodium lactate, hydroxypropyl methylcellulose, tetrasodium EDTA, fragrance, hydrolyzed oat protein, carthamus tinctorius (safflower) seed oil, citric acid, sodium chloride, methylchloroisothiazolinone, methylisothiazolinone.

**Properties:** Phyto P anti-itch shampoo is formulated for the temporary relief of itching in dogs, cats, and horses. This low-lather formula contains pramoxine, a mild numbing agent, as well as colloidal oatmeal and essential fatty acids to soothe irritated skin. It also contains phytosphingosine, a proceramide to help moisturize and support a healthy skin barrier.

**Indications:** For the temporary relief of itching and skin irritations.

**Directions for use:** Use 2-3 times per week until symptoms subside or as directed by your veterinarian. Wet the animal with cool water from the neck down and apply shampoo first on the areas with skin abnormalities. 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. Leave shampoo on for 10 minutes before rinsing with cool water. Follow bath with Phyto P anti-itch créme rinse. For a rinse-free solution between baths, ask your veterinarian about Phyto P spray or 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: 11695-7224-8

Phyto P

Pramoxine HCl 1%,

phytosphingosine salicyloyl 0.05%

#### Anti-Itch Shampoo

Soothing shampoo for dogs, cats and horses

For animal use only

Net contents: 8 fl oz (237 mL)

#### covetrus 🕏

NDC: 11695-7224-8

# Phyto P

Pramoxine HCl 1%, phytosphingosine salicyloyl 0.05%

Anti-itch Shampoo

Soothing shampoo for dogs, cats, and horses

For animal use only Keep out of reach of children

Net contents: 8 fl oz (237 mL)

Active ingredients: Pramoxine HCl 1%, phytosphingosine salicyloyl 0.05%.

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

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Storage: Store at room temperature. Do not freeze.

Reorder #038190 Questions? (855) 724-3461 AH-038190-02 REV: 0819

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

F41710D-US 18-01-v2

#### PRINCIPAL DISPLAY PANEL - 16 fl oz (473 mL)

covetrus

NDC: 11695-7224-6

Phyto P

Pramoxine HCl 1%,

phytosphingosine salicyloyl 0.05%

**Anti-Itch Shampoo** 

Soothing shampoo for dogs, cats and horses

For animal use only

Keep out of reach of children

Net contents: 16 fl oz (473 mL)



NDC: 11695-7224-6

## Phyto P

Pramoxine HCl 1%, phytosphingosine salicyloyl 0.05%

**Anti-itch Shampoo** 

Soothing 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: Pramoxine HCl 1%, phytosphingosine salicyloyl 0.05%.

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

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Storage: Store at room temperature. Do not freeze.

Reorder #038191 Questions? (855) 724-3461 AH-038191-02 REV: 0819 Distributed by: Covetrus North America 400 Metro Place North Dublin, OH 43017 covetrus.com



F41730D-US 18-P1-v2

#### PRINCIPAL DISPLAY PANEL - 1 gallon (3.875 L)

covetrus

NDC: 11695-7224-1

Phyto P

Pramoxine HCl 1%,

phytosphingosine salicyloyl 0.05%

Anti-Itch Shampoo

Soothing shampoo for dogs, cats and horses

For animal use only

Keep out of reach of children

Net contents: 1 gallon (3.785 L)



NDC: 11695-7224-1

# Phyto P

Pramoxine HCl 1%, phytosphingosine salicyloyl 0.05%

Anti-itch Shampoo

Soothing 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: Pramoxine HCl 1%, phytosphingosine salicyloyl 0.05%.

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

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Storage: Store at room temperature. Do not freeze.

Reorder #039615 Questions? (855) 724-3461 AH-039615-02 REV: 0819 Distributed by: Covetrus North America 400 Metro Place North Dublin, OH 43017 covetrus.com



F41720D-US 18-Q1-v2

#### PHYTO P ANTI-ITCH

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pramoxine hydrochloride, phytosphingosine salicyloyl shampoo

ı	Product information			
	Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:11695-7224
l	Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
PRAMO XINE HYDRO CHLO RIDE (UNII: 88 AYB867L5) (PRAMO XINE - UNII: 068 X84E056)	PRAMOXINE HYDROCHLORIDE	10 mg in 1 mL	
SALICYLOYL PHYTOSPHINGOSINE (UNII: U891J4JCNH) (PHYTOSPHINGOSINE - UNII:GIN46U9Q2Q)	SALICYLOYL PHYTOSPHINGOSINE	0.5 mg in 1 mL	

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)		
COCAMIDO PRO PYL BETAINE (UNII: 50 CF3011KX)		
DISO DIUM CO CO AMPHO DIACETATE (UNII: 18 L9 G3 U5 1M)		
GLYCERIN (UNII: PDC6A3C0OX)		

SODIUM LACTATE (UNII: TU7HW0W0QT)		
HYPROMELLOSES (UNII: 3NXW29 V3WO)		
EDETATE SO DIUM (UNII: MP1J8 420 LU)		
SODIUM CHLORIDE (UNII: 451W47IQ8X)		
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)		
OATMEAL (UNII: 8PI54V663Y)		
SAFFLOWER OIL (UNII: 65UEH262IS)		
METHYLCHLORO ISO THIAZO LINO NE (UNII: DEL7T5 QRPN)		
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)		

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11695-7224-8	237 mL in 1 BOTTLE, PLASTIC		
2	NDC:11695-7224-6	473 mL in 1 BOTTLE, PLASTIC		
3	NDC:11695-7224-1	3785 mL in 1 JUG		

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

### 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