

CERASOOTHE- pramoxine hydrochloride 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](#).

CeraSoothe

PRAMOXINE

Anti-Itch Shampoo

Fragrance: Cucumber melon

Pramoxine HCl 1%

Formulated for cats, dogs and horses

A conditioning shampoo with pramoxine to help relieve itching and skin irritations. Ceramides and avenanthramides are skin nourishing nutrients that moisturize and calm the skin. They also support the skin's natural immune system and provide building blocks for renewed skin barrier integrity.

Active ingredient: Pramoxine HCl 1%.

Inactive ingredients: Water, sodium C14-16 olefin sulfonate, PEG-7 glyceryl cocoate, sodium chloride, disodium cocoamphodiacetate, cocamidopropyl betaine, glycerin, sodium lactate, avena sativa (oat) kernal extract, ceramide EOP, ceramide EOS, ceramide NP, carthamus tinctorius (safflower) seed oil, PEG-8, laurate, laureth-4, fragrance, citric acid, potassium sorbate, methylchloroisothiazolinone, methylisothiazolinone.

Indications: For use on cats, dogs and horses for the temporary relief of itching and skin irritations.

Directions for use: Bathe 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 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. Wash hands after use. For a rinse-free solution between baths, use Ceraven Pramoxine anti-itch mousse.

Cautions: For external use on cats, dogs and horses only. Avoid contact with 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.

STORAGE CONDITIONS: Store at room temperature. Do not freeze.

Distributed by:

Covetrus North America

400 Metro Place North

Dublin, OH 43017

covetrus.com

QUESTIONS?

(855) 724-3461

PRINCIPAL DISPLAY PANEL - 8 OUNCE (237 mL) Bottle

Inspired by veterinarians

CeraSoothe

PRAMOXINE

Anti-itch Shampoo

Fragrance: Cucumber melon

Pramoxine HCl 1%

Formulated for cats, dogs and horses

Keep out of reach of children

For animal use only

NDC: 11695-6984-1

Net contents: 8 fl oz (237 mL)

Inspired by veterinarians



Anti-Itch Shampoo

Fragrance: Cucumber melon

Pramoxine HCl 1%



Formulated for cats, dogs, and horses

Keep out of reach of children
For animal use only

NDC: 11695-6984-1

Net contents: 8 fl oz (237mL)



A conditioning shampoo with pramoxine to help relieve itching and skin irritations. Ceramides and avenanthramides are skin nourishing nutrients that moisturize and calm the skin. They also support the skin's natural immune system and provide building blocks for renewed skin barrier integrity.

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Storage: Store at room temperature. Do not freeze.

Reorder #073117

Questions?

(855) 724-3461

AH-073117-02

REV: 0621

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Covetrus North America

400 Metro Place North

Dublin, OH 43017

covetrus.com



G41010C-US 18-01-v4

(01)00840066511047

PRINCIPAL DISPLAY PANEL - 16 OUNCE (473 mL) Bottle

Inspired by veterinarians

CeraSoothe

PRAMOXINE

Anti-itch Shampoo

Fragrance: Cucumber melon

Pramoxine HCl 1%

Formulated for cats, dogs and horses

Keep out of reach of children

For animal use only

NDC: 11695-6984-2

Net contents: 16 fl oz (473 mL)



Anti-Itch Shampoo

Fragrance: Cucumber melon

Pramoxine HCl 1%



Formulated for cats, dogs, and horses

Keep out of reach of children
For animal use only

NDC: 11695-6984-2

Net contents: 16 fl oz (473mL)



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Storage: Store at room temperature. Do not freeze.

Reorder #073116

Questions?
(855) 724-3461

AH-073116-02
REV: 0621

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



G41020C-US 18-P1-v4

CERASOOTHE

pramoxine hydrochloride shampoo

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:11695-6984
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)	

PEG-7 GLYCERYL COCOATE (UNII: VNX7251543)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
DISODIUM COCOAMPHODIACETATE (UNII: 18L9G3U51M)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM LACTATE (UNII: TU7HW0W0QT)	
AVENANTHRAMIDES (UNII: 5PA41O4AIT)	
CERAMIDE 1 (UNII: 5THT33P7X7)	
CERAMIDE EOS (UNII: CROJ8RN66K)	
CERAMIDE NP (UNII: 4370DF050B)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
PEG-8 LAURATE (UNII: 762O8IWA10)	
LAURETH-4 (UNII: 6HQ855798J)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11695-6984-1	237 mL in 1 BOTTLE, PLASTIC		
2	NDC:11695-6984-2	473 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/02/2021	

Labeler - BUTLER ANIMAL HEALTH SUPPLY, LLC DBA COVETRUS NORTH AMERICA (603750329)

Registrant - Ceva Sante Animale (261126049)

Revised: 5/2022

BUTLER ANIMAL HEALTH SUPPLY, LLC DBA COVETRUS NORTH AMERICA