## CERASOOTHE KET- ketoconazole 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.

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CeraSoothe KET

Antiseptic Flush

Fragrance free

Ketoconazole 0.1%

Formulated for cats and dogs

## Keep out of reach of children

For animal use only

A gentle antifungal and antibacterial skin and ear cleansing solution. Ketoconazole fights yeast and fungi. Tromethamine (TRIS) helps break down bacteria cell walls. 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 ingredients:** Ketoconazole 0.1%.

**Inactive ingredients:** Water, SD Alcohol 40-B, nonoxynol-9, disodium EDTA, tromethamine, avena sativa (oat) kernal extract, glycerin, ceramide EOP, ceramide EOS, ceramide NP, potassium sorbate, methylisothiazolinone.

Indications: For use on cats and dogs for the antiseptic cleansing of skin and ears.

**Directions for use:** Apply twice a day or as directed by your veterinarian. Wash hands after use.

<u>Ear cleaning:</u> Moisten a cotton ball with solution and place in entrance of ear canal, or hold the ear flap upwards and fill the ear canal 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 debris and excess solution with a clean, dry cotton ball.

<u>Skin cleaning:</u> Moisten absorbent material with solution and gently wipe the area to clean and remove debris. Repeat as necessary until clean.

**Cautions:** For external use on dogs or cats only. Avoid contact with the 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 in the case of a suspected ruptured eardrum.

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

**Questions?** 

(855) 724-3461

Distributed by:

### PRINCIPAL DISPLAY PANEL - 4 OUNCE (118 mL) Bottle

Inspired by veterinarians

### CeraSoothe KET

## **Antiseptic Flush**

Fragrance free

Ketoconazole 0.1%,

Formulated for cats and dogs

### Keep out of reach of children

For animal use only

NDC 11695-6979-1

Net contents: 4 fl oz (118 mL)

Inspired by veterinarians

A gentle antifungal and antibacterial skin and ear cleansing solution. Ketoconazole fights yeast and fungi. Tromethamine (TRIS) helps break down bacteria cell walls. 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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Reorder #073107 Questions? (855) 724-3461 AH-073107-02 REV: 0621

G40410F-US 18-V1-v4

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



Indications: For use on cats and dogs for the antiseptic cleansing of skin and ears.

**Directions for use:** Apply twice a day or as directed by your veterinarian. Wash hands after use.

Ear cleaning: Moisten a cotton ball with solution and place in entrance of ear canal, or hold the ear flap upwards and fill the ear canal 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 debris and excess solution with a clean, dry cotton ball.

Skin cleaning: Moisten absorbent material with solution and gently wipe the area to clean and remove debris. Repeat as necessary until clean.

Cautions: For external use on cats and dogs 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.

Storage: Store at room temperature. Do not freeze.

## PRINCIPAL DISPLAY PANEL - 16 OUNCE (473 mL) Bottle

Inspired by veterinarians

# CeraSoothe KET Antiseptic Flush

Fragrance free

Ketoconazole 0.1%,

Formulated for cats and dogs

## Keep out of reach of children

For animal use only

NDC 11695-6979-2

Net contents: 16 fl oz (473 mL)

Inspired by veterinarians



# **Antiseptic Flush**

Fragrance free

Ketoconazole 0.1%



Formulated for cats and dogs

Keep out of reach of children For animal use only



Net contents: 16 fl oz (473mL)



A gentle antifungal and antibacterial skin and ear cleansing solution. Ketoconazole fights yeast and fungi. Tromethamine (TRIS) helps break down bacteria cell walls. 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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Inactive ingredients: Water, SD alcohol 40-B, nonoxynol-9, disodium EDTA, tromethamine, avena sativa (oat) kernel extract, glycerin, ceramide EOP, ceramide EOS, ceramide NP, potassium sorbate, methylisothiazolinone.

Indications: For use on cats and dogs for the antiseptic cleansing of skin and ears.

Directions for use: Apply twice a day or as directed by your veterinarian. Wash hands after use.

Ear cleaning: Moisten a cotton ball with solution and place in entrance of ear canal, or hold the ear flap upwards and fill the ear canal 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 debris and excess solution with a clean, dry cotton ball.

Skin cleaning: Moisten absorbent material with solution and gently wipe the area to clean and remove debris. Repeat as necessary until

Cautions: For external use on cats and dogs 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.

Storage: Store at room temperature. Do not freeze.

Reorder #073106 Questions? (855) 724-3461

Questions? (855) 724-3461 AH-073106-02 REV: 0621 Distributed by: Covetrus North America 400 Metro Place North Dublin, OH 43017 covetrus.com

G40430F-US 18-P1-v4



#### CERASOOTHE KET

ketoconazole solution

Product Information				
Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:11695-6979	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety		
Ingredient Name	<b>Basis of Strength</b>	Strength

KETOCONAZOLE (UNII: R9400W927I) (KETOCONAZOLE - UNII:R9400W927I) KETOCONAZOLE 1 mg in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
ALCOHOL (UNII: 3K9958V90M)		
NONOXYNOL-9 (UNII: 48Q180SH9T)		
EDETATE DISODIUM (UNII: 7FLD91C86K)		
TROMETHAMINE (UNII: 023C2WHX2V)		
AVENANTHRAMIDES (UNII: 5PA41O4AIT)		
GLYCERIN (UNII: PDC6A3C0OX)		
CERAMIDE 1 (UNII: 5THT33P7X7)		
CERAMIDE EOS (UNII: CROJ8RN66K)		
CERAMIDE NP (UNII: 4370DF050B)		
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)		
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)		

P	Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date	
1	NDC:11695-6979-1	118 mL in 1 BOTTLE, PLASTIC			
2	NDC:11695-6979-2	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