VETRASEB CERADERM TRIS- ketoconazole solution MWI/VETONE

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.

VetraSeb™ CeraDerm™ TRIS

Flush

Ketoconazole 0.1%

Antiseptic Solution for Dogs or Cats

For veterinary use only

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.

PROPERTIES: A gentle antifungal and antibacterial skin and ear cleansing solution. Ketoconazole fights yeast and fungi. TRIS helps break down bacteria cell walls. Skin nourishing nutrients moisturize and calm the skin. They also support the skin's natural immune system and provide building blocks for renewed skin barrier integrity.

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

DIRECTIONS FOR USE:

SKIN CLEANING: Apply twice a day or as directed by your veterinarian. Moisten absorbent material with solution and gently wipe the area to clean and remove debris. Repeat as necessary until clean. Wash hands after use.

EAR CLEANING: Ask your veterinarian which of these protocols is best for your pet. 1) Moisten a cotton ball with solution and place in entrance of ear canal; **OR** 2) Hold the ear flap upwards 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 debris and excess solution with a clean cotton ball. Wash hands after use.

CAUTIONS: For external use on dogs or cats 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 in the case of a suspected ruptured eardrum.

WARNING: Keep out of reach of children.

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

Available only through your veterinarian.

Distributed by: MWI Boise, Idaho 83705

www.VetOne.net

PRINCIPAL DISPLAY PANEL - 4 OUNCE (118 mL) Bottle

VetOne®

VetraSeb™ CeraDerm™ TRIS

Flush

Ketoconazole 0.1%

Antiseptic Solution for Dogs and Cats

For veterinary use only

Net contents: 4 FL OZ (118 mL)



PRINCIPAL DISPLAY PANEL - 16 OUNCE (473 mL) Bottle

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Distributed by: MW Boise, Idaho 83705 www.VetOne.net Questions? 1-800-999-0297 Rev. 02/21

NDC 13985-441-16 G40430E 18-P1-v3

VETRASEB CERADERM TRIS

ketoconazole solution

Product Information

Product Type OTC ANIMAL DRUG Item Code (Source) NDC:13985-441

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength 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	Marketing Start Date	Marketing End Date		
1	NDC:13985-441-04	118 mL in 1 BOTTLE, PLASTIC				
2	NDC:13985-441-06	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 - MWI/VETONE (019926120)

Registrant - Ceva Sante Animale (261126049)

Revised: 4/2021 MW/VETONE