SUFFUSION TRIS- ketoconazole solution ASPEN VETERINARY RESOURCES

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.

Suffusion™ TRIS

FOR DOGS AND CATS

Ketoconazole 0.1%

ANTISEPTIC FLUSH

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.

INDICATIONS: 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.

<u>Ear Cleaning:</u> 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 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. Wash hands after use.

CAUTIONS: For external use on dogs and 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.

WARNING: Keep out of reach of children.

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

QUESTIONS? 1-800-999-0297

Pivetal

Distributed by:

Aspen Veterinary Resources ®, LTD.

Liberty, MO 64068

pivetalvet.com

PRINCIPAL DISPLAY PANEL - 4 OUNCE (118 mL) Bottle

Pivetal

NDC 46066-079-88

Suffusion™ TRIS

FOR DOGS AND CATS

Ketoconazole 0.1%

ANTISEPTIC FLUSH

4 fl oz (118 mL)



PRINCIPAL DISPLAY PANEL - 16 OUNCE (473 mL) Bottle

Pivetal

NDC 46066-079-91

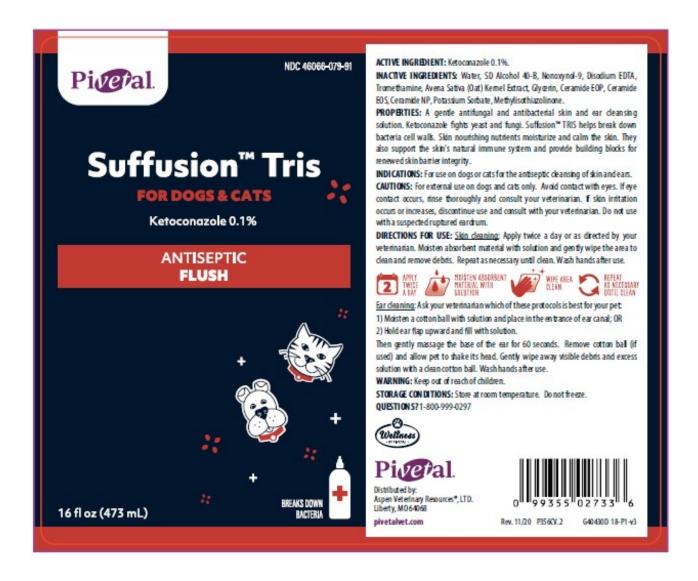
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Ketoconazole 0.1%

ANTISEPTIC FLUSH

16 fl oz (473 mL)



SUFFUSION TRIS

ketoconazole solution

Product Information Product Type OTC ANIMAL DRUG Item Code (Source) NDC:46066-079

Route of Administration TOPICAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength KETOCONAZOLE (UNII: R9400W927I) (KETOCONAZOLE - UNII:R9400W927I) KETOCONAZOLE (UNII: R9400W927I) (Temporal of the context of the con

| 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:46066-079-88 | 118 mL in 1 BOTTLE, PLASTIC | | | |
| 2 | NDC:46066-079-91 | 473 mL in 1 BOTTLE, PLASTIC | | | |

| Marketing Start Date | Marketing End Date |
|-------------------------|-----------------------|
| 04/02/2021 | |
| | Date |

Labeler - ASPEN VETERINARY RESOURCES (627265361)

Registrant - Ceva Sante Animale (261126049)

Revised: 4/2021 ASPEN VETERINARY RESOURCES