

SUFFUSION TRIS FLUSH- ketoconazole, phytosphingosine hydrochloride solution
Aspen Veterinary Resource, LTD.

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 +PS FLUSH

ACTIVE INGREDIENTS: Ketoconazole 0.1%, Phytosphingosine HCl 0.01%.

INACTIVE INGREDIENTS: Water, SDA 40B 190 Proof, Nonoxynol-9, Disodium EDTA, Tromethamine, Methylisothiazolinone.

PROPERTIES: Suffusion TRIS +PS Flush is an antibacterial and antifungal solution for the gentle cleansing of skin and ears. It contains ketoconazole for the management of yeast and fungal infections. TRIS +PS Flush helps break down bacteria cell walls. It also contains phytosphingosine, a pro-ceramide to help moisturize and support a healthy skin barrier.

INDICATIONS: For the antiseptic cleansing of skin and ears on dogs and cats.

DIRECTIONS FOR USE: Shake well before use. Apply twice a day or as directed by your veterinarian. Ask your veterinarian which of the following protocols is best for your pet.

Ear cleaning: 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. Skin cleaning: Apply liberally then use absorbent material to gently wipe away excess solution and debris. Repeat as necessary until clean. Do not allow animal to lick the treated area.

CAUTIONS: For external use on dogs and 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 with a suspected ruptured eardrum. Wash hands after use.

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
www.pivetalvet.com

PRINCIPAL DISPLAY PANEL - 4 OUNCE (118 mL) Bottle

NDC 46066-166-80

SUFFUSION™

TRIS +PS Flush

Ketoconazole 0.1%,

Phytosphingosine HCl 0.01%

Antiseptic Solution



FOR DOGS & CATS

Phytosphingosine

Wellness

• BY PIVETAL •

4 FL. OZ. (118 mL)

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PRINCIPAL DISPLAY PANEL - 16 OUNCE (473 mL) Bottle

NDC 46066-166-91

SUFFUSION™

TRIS +PS Flush

Ketoconazole 0.1%,

Phytosphingosine HCl 0.01%

Antiseptic Solution

FOR DOGS & CATS

Phytosphingosine

Wellness

• BY PIVETAL •

16 FL. OZ. (473 mL)

SUFFUSION™

TRIS +PS Flush

Ketoconazole 0.1%,
Phytosphingosine HCl 0.01%

Antiseptic Solution
FOR CATS & DOGS



Phytosphingosine



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Pivotal

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Liberty, MO 64068
www.pivotalvet.com

Rev. 07/19 P130CV



F40230G-US 18-P1-v2

SUFFUSION TRIS FLUSH

ketoconazole, phytosphingosine hydrochloride solution

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:46066-166
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
PHYTOSPHINGOSINE HYDROCHLORIDE (UNII: TT871XV7TU) (PHYTOSPHINGOSINE - UNII:GIN46U9Q2Q)	PHYTOSPHINGOSINE HYDROCHLORIDE	0.1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
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WATER (UNII: 059QF0K00R)	
ALCOHOL (UNII: 3K9958V90M)	
NONOXYNOL-9 (UNII: 48Q180SH9T)	
TROMETHAMINE (UNII: 023C2WHX2V)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46066-166-80	118 mL in 1 BOTTLE, PLASTIC		
2	NDC:46066-166-91	473 mL in 1 BOTTLE, PLASTIC		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/04/2019	

Labeler - Aspen Veterinary Resource, LTD. (627265361)

Registrant - Ceva Sante Animale (261126049)

Establishment			
Name	Address	ID/FEI	Business Operations
Evonik Nutrition & Care GmbH		314906476	api manufacture

Revised: 9/2019

Aspen Veterinary Resource, LTD.