ANTIBACTERIAL AND ANTIFUNGAL MEDICATED TRIS FLUSHketoconazole solution Alpha Paw Inc

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.

ANTIBACTERIAL & ANTIFUNGAL MEDICATED TRIS FLUSH

ACTIVE INGREDIENTS

Ketoconazole......0.1%

ANTIBACTERIAL & ANTIFUNGAL MEDICATED TRIS FLUSH For Dogs & Cats

FIGHT FUNGUS!

Say goodbye to pesky ear infections. Treatment is as easy as point, squeeze and soothe. Skin conditions that are responsive to Ketoconazole stand no chance against this powerful formula. Non-irritating formula ensures pets are comfortable.

INACTIVE INGREDIENTS

Water, SD Alcohol-40B, Nonoxynol-9, Disodium EDTA, Benzyl Alcohol, Fragrance, Tromethamine Technical Grade.

PRECAUTIONS

For topical use on animals only. Avoid contact with eyes, or mucous membranes. If eye contact occurs, rinse thoroughly with water and consult a veterinarian. Do not allow the animal to directly inhale the spray. If undue skin irritation develops or increases, discontinue use and consult a veterinarian.

DIRECTIONS

Shake well before use. Apply liberally to the affected area(s). Apply twice daily or as directed by veterinarian. Use cotton or absorbent material to clean excess solution and wipe away debris. Do not allow the animal to lick the treated area until dry to prevent ingestion. Wash hands after use.

STORAGE

Store at controlled room temperature; protect from freezing.

Contains ketoconazole Manages fungal activity Gentle flushing of ears & skin Antiseptic & antifungal solution GENTLE ON SKIN CHOSEN BY TOP VETS FOR DOGS AND CATS

ALPHA PAW Questions or Comments: Call (800) 363-5458 www.alphapaw.com Alpha Paw LLC, Las Vegas NV 89139

Packaging

Package 12oz 355mL

alpha paw

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For Dogs & Cats

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ANTIBACTERIAL & ANTIFUNGAL



For Dogs & Cats

MEDICATED TRIS FLUSH

Contains ketoconazole

Manages fungal activity

Gentle flushing of ears & skin

Antiseptic & antifungal solution

Made in the USA

12oz 355 ml







ACTIVE INGREDIENTS

Ketoconazole......

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ANTIBACTERIAL AND ANTIFUNGAL MEDICATED TRIS FLUSH

ketoconazole solution

Product Information

Product Type OTC ANIMAL DRUG Item Code (Source) NDC:86175-005

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

KETOCONAZOLE (UNII: R9400W927I) (KETOCONAZOLE - UNII:R9400W927I) KETOCONAZOLE 0.1 g in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
ALCOHOL (UNII: 3K9958V90M)		
NONOXYNOL-9 (UNII: 48Q180SH9T)		
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)		
BENZYL ALCOHOL (UNII: LKG8494WBH)		
TROMETHAMINE (UNII: 023C2WHX2V)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86175-005- 12	355 mL in 1 CONTAINER		
2	NDC:86175-005- 24	1 in 1 PACKAGE		
2		355 mL in 1 CONTAINER; Number of Units = 2		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/03/2022	

Labeler - Alpha Paw Inc (117036685)

Establishment Name Address ID/FEI Business Operations Tropichem Research Labs, LLC dba Vetio 603123068 manufacture

Establishment			
Name	Address	ID/FEI	Business Operations
Piramal Pharma Limited		919067108	api manufacture

Establishment			
Name	Address	ID/FEI	Business Operations
Sharon Bio-Medicine Limited		675472749	api manufacture

Revised: 3/2023 Alpha Paw Inc