# ANTIBACTERIAL ANTIFUNGAL MEDICATED- chlorhexidine gluconate, ketoconazole shampoo 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.

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#### **ANTIBACTERIAL & ANTIFUNGAL MEDICATED SHAMPOO**

#### **ACTIVE INGREDIENTS**

Chlorhexidine Gluconate	2%
Ketoconazole	1%

ANTIBACTERIAL & ANTIFUNGAL MEDICATED SHAMPOO For Dogs & Cats

#### **DITCH THE ITCH!**

Kiss itch and irritation goodbye for your scratchy pets. Treatment is as easy as lather, rinse and soothe. Skin conditions that are responsive to Ketoconazole and Chlorhexidine stand no chance against this powerful formula. Vitamin E and essential fatty acids follow close behind to ensure that treated skin is nourished.

#### **INACTIVE INGREDIENTS**

Water, Lauramine Oxide, Cocamidopropyl Betaine, Polyacrylate-1 Crosspolymer, Decyl Glucoside, Glycolic Acid, Fragrance, Tetrasodium EDTA, Methylchloroisothiazolinone, Methylisothiazolinone.

#### **PRECAUTIONS**

Avoid contact with eyes or mucous membranes. If eye contact occurs, rinse thoroughly with water and consult a veterinarian. Not for otic use. Wash hands after using.

#### **DIRECTIONS**

Shake well before use. Wet the hair coat with warm water and apply a sufficient amount of shampoo to create a rich lather. Massage shampoo into wet hair coat, lather freely. Rinse and repeat. Allow shampoo to remain on hair for 5 to 10 minutes, then rinse thoroughly with clean water. May be used initially 2 to 3 times a week for 4 weeks, then reducing to once a week, or as directed by your veterinarian.

#### **CAUTIONS**

If undue skin irritation develops or increases, discontinue use and consult a veterinarian.

#### **STORAGE**

Store at controlled room temperature.

Contains chlorhexidine & ketoconazole Freshens & deodorizes Treatment for dry, itchy irritated skin Removes yeast, bacteria, fungus & ringworm

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 473mL

# alpha paw



For Dogs & Cats

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MEDICATED SHAMPOO

Contains chlorhexidine & ketoconazole
Freshens & deodorizes

Treatment for dry, itchy irritated skin
Removes yeast, bacteria, fungus & ringworm

Made in the USA 16oz 473 ml







ACTIVE INGREDIENTS

Chlorhexidine Gluconate......2
Ketoconazole......1

INACTIVE INGREDIENTS: Water, Lauramine
Oxide, Cocamidopropyl Betaine, Polyacrylate-1
Crosspolymer, Decyl Glucoside, Glycolic Acid,
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### chlorhexidine gluconate, ketoconazole shampoo

Product Type OTC ANIMAL DRUG Item Code (Source) NDC:86175-002

**Route of Administration** TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	2 g in 100 mL		
KETOCONAZOLE (UNII: R9400W927I) (KETOCONAZOLE - UNII:R9400W927I)	KETOCONAZ OLE	1 g in 100 mL		

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
LAURAMINE OXIDE (UNII: 4F6FC4MI8W)	
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)	
POLYACRYLATE-1 CROSSPOLYMER (UNII: R5P9Z5WD6D)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
EDETATE SODIUM (UNII: MP1J8420LU)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	

Product Characteristics				
Color	orange (pink)	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:86175-002- 16	473 mL in 1 BOTTLE, PLASTIC			
2	NDC:86175-002- 32	1 in 1 PACKAGE			
2		473 mL in 1 BOTTLE, PLASTIC; Number of Units = 2			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
unapproved drug		10/02/2022			

other 10/03/2022

## Labeler - Alpha Paw Inc (117036685)

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

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
Garonit Pharmaceutical, Inc		800875106	api manufacture

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
Unilab Chemicals and Pharmaceuticals Private Limited		915893696	api manufacture

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Cadila Pharmaceuticals Limited		916130698	api manufacture	

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

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

Revised: 3/2023 Alpha Paw Inc