# 0.1% KETOCONAZOLE, 0.15% SALICYLIC ACID- ear rinse solution, gel forming / drops

### Sergeant's Pet Care Products LLC

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.

-----

## PetArmor Ear Rinse for dogs and cats

PetArmor® Ear Rinse

For Dogs and Cats

Aid in drying or cleansing

Gently cleans away dirt and was

**PetArmor**® **Ear Rinse** can be used for gentle flushing and cleansing of skin and ears in conditions where an antibacterial and antifungal formulation is indicated. It also lowers the pH in the ear to inhibit bacterial growth.

#### **ACTIVE INGREDIENTS:**

0.1% Ketoconazole, 0.15% Salicylic Acid

#### **INACTIVE INGREDIENTS:**

Purified Water, Propylene Glycol, Glycerin, Polysorbate 20, Lactic Acid, Ale Barbadensis (Aloe Vera) Leaf Juice, Methylisothiazolinone, Nonoxynol-9, Sodium Hydroxide

#### **Directions for Use:**

SHAKE WELL. For use as an ear flush: apply to the ear canal and gently, but firmly, massage the base of the ear. Use a cotton ball to remove excess solution. Repeat as necessary or as directed by your veterinarian. Close cap tightly for storage.

#### **CAUTION:**

For topical use only. Do not use on severely irritated skin – contact your veterinarian. If skin irritation develops or increases or you see no improvement, stop use and call your veterinarian. Keep out of reach of children and pets. Wash hands after use.

Store at controlled room temperature of 15 - 30° C (59 - 86° F).

Questions or medical emergency: 1-800-224-7387

#### P007263 AHII

PetArmor® Ear Rinse can be used for gentle flushing and cleansing of skin and ears in conditions where an antibacterial and antifungal formulation is indicated. It also lowers the pH in the ear to inhibit bacterial growth. ACTIVE INGREDIENTS: 0.1% Ketoconazole, 0.15% Salicylic Acid INACTIVE INGREDIENTS: Purified Water, Propylene Glycol, Glycerine, Polysorbate-20, Lactic Acid, Aloe Barbadensis (Aloe Vera) Leaf Juice, Fragrance, Methylisothiazolinone, Nonaxynol-9, Sodium Hydroxide **Directions for Use:** 

SHAKE WELL. For use as an ear flush: apply to the ear canal and gently, but firmly, massage the base of the ear. Use a cotton ball to remove excess solution. Repeat as necessary or as directed by your veterinarian. Close cap tightly for storage.

CAUTION: For topical use only. Do not use on severely irritated skin - contact your veterinarian. If skin irritation develops or increases or you see no improvement, stop use and call your veterinarian. Keep out of reach of children and pets. Wash hands after use.

Store at controlled room temperature of 15-30° C (59 - 86° F).

Distributed by: Sergeant's Pet Care Products, Inc. Omaha, NE 68138

Questions or medical emergency: 1-800-224-7387

petarmor.com







## 0.1% KETOCONAZOLE, 0.15% SALICYLIC ACID

ear rinse solution, gel forming / drops

#### **Product Information**

**Product Type** OTC ANIMAL DRUG Item Code (Source) NDC:21091-269

**Route of Administration** AURICULAR (OTIC)

## **Active Ingredient/Active Moiety**

Ingredient Name	<b>Basis of Strength</b>	Strength
KETOCONAZOLE (UNII: R9400W927I) (KETOCONAZOLE - UNII:R9400W927I)	KETOCONAZ OLE	0.1
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII: O414PZ4LPZ)	SALICYLIC ACID	0.15

## **Inactive Ingredients Ingredient Name** Strength WATER (UNII: 059QF0KO0R) PROPYLENE GLYCOL (UNII: 6DC9Q167V3) **GLYCERIN** (UNII: PDC6A3C0OX) POLYSORBATE 20 (UNII: 7T1F30V5YH) LACTIC ACID (UNII: 33X04XA5AT) ALOE VERA LEAF (UNII: ZY81Z83H0X) METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA) NONOXYNOL-9 (UNII: 48Q180SH9T) **SODIUM HYDROXIDE** (UNII: 55X04QC32I)

#### **Product Characteristics**

Color	white	Score
Shape		Size
Flavor		Imprint Code
Contains		

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21091-269-01	1 in 1 CONTAINER		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		11/08/2023		

## Labeler - Sergeant's Pet Care Products LLC (876995171)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
SV Labs Prescott Corporation		185073996	manufacture

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

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
Sigma-Aldrich Manufacturing LLC		829643423	api manufacture

Revised: 4/2024 Sergeant's Pet Care Products LLC