BENZALKONIUM CHLORIDE- hot spot skin remedy gel Sergeants 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.

SENTRY Hot Spot Skin Remedy

ACTIVE INGREDIENT:

Benzalkonium Chloride

PURPOSE: SENTRY Hot Spot Skin Remedy for dogs is formulated to be effective for skin irritations. Specifically kills *staphylococcus intermedius* bacteria. Hot spots in dogs are commonly associated with *staphylococcus intermedius*. Kills topical bacteria, fungus and viruses. SENTRY Hot Spot Skin Remedy is indicated for superficial cuts, scrapes, and abrasions. Best of all, SENTRY Hot Spot Skin Remedy contains no alcohol and is a non-stinging formula.

Signs of Hot Spots: Hot spots are usually accompanied by incessant rubbing, scratching and biting due to intense itching. Other signs are moist reddened areas, hair loss, and flaky skin. Hot spots are usually warm to the touch.

WARNINGS:

Do not use on puppies under 6 weeks of age.

For external use only on dogs.

KEEP OUT OF REACH OF CHILDREN AND PETS

DIRECTIONS FOR USE:

Trim the hair around the sore. Wash the area with mild soap and water, rinse and pat dry. Apply to affected area using the applicator tip. Does not require dabbing on with a cotton ball. Consult a veterinarian if any problems persist or are of concern.

Store below 30°C (86°F)

INACTIVE INGREDIENTS:

Allantoin, Cetrimonium Chloride, Citric Acid, Cocamidopropyl Betain, Green 5 (Cl 61570), Hydroxypropyl Methyloellubse, Methylparaben, Octoxynol 9, Propylene Glycol, Propylparaben, Sodium Hydroxide, Triethanolamine. Water.

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

hot spot skin remedy gel Product Information Product Type OTC ANIMAL DRUG Item Code (Source) NDC:21091-001 Route of Administration

Active Ingredient/Active Moiety Ingredient Name BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y) BENZALKONIUM CHLORIDE 0.13 g in 118 mL

Inactive Ingredients		
Ingredient Name	Strength	
ALLANTOIN (UNII: 344S277G0Z)		
CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)		
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)		
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)		
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)		
HYPROMELLOSES (UNII: 3NXW29V3WO)		
METHYLPARABEN (UNII: A2I8C7HI9T)		
OCTOXYNOL 9 (UNII: 7JPC6Y25QS)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
PROPYLPARABEN (UNII: Z8IX2SC10H)		
SODIUM HYDROXIDE (UNII: 55X04QC32I)		
TROLAMINE (UNII: 903K93S3TK)		
WATER (UNII: 059QF0KO0R)		

Product Characteristics			
Color	blue (blue/green)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21091-001-01	118 mL in 1 BOTTLE, PLASTIC		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/17/2022	

Labeler - Sergeants Pet Care Products LLC (876995171)

Establishment				
Name	Address	ID/FEI	Business Operations	
Lonza Biologics Inc		093149750	api manufacture	

Establishment				
Name	Address	ID/FEI	Business Operations	
Straight Arrow Products Inc		052165154	manufacture, label, pack	