

STRAWFIELD PETS ANTI-ITCH MEDICATED WITH PRAMOXINE HYDROCHLORIDE- pramoxine hydrochloride shampoo NEXTMUNE AB

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.

NEXTMUNE AB - ANTI-ITCH MEDICATED SHAMPOO WITH PRAMOXINE HYDROCHLORIDE (86127-102)

ACTIVE INGREDIENTS

PRAMOXINE HYDROCHLORIDE....1%

<p>Drug Facts</p>	 <p>ANTI-ITCH MEDICATED SHAMPOO with pramoxine hydrochloride</p> <p>COCONUT LIME VERBENA</p> <p>A SOOTHING SOAP-FREE ANTI-ITCH FORMULA WITH OATMEAL & SAFFLOWER OIL</p>		<p>BROAD SPECTRUM VETERINARY FORMULA</p>
<p>Active Ingredients</p> <p>Pramoxine Hydrochloride.....1% Topical Anesthetic</p>			<p>ANTI-ITCH MEDICATED SHAMPOO A soap-free formula designed for cats, dogs and horses blended with hydrolyzed oats and safflower oil to moisturize the skin barrier. Healthy hydrated skin is resistant to infection, dandruff, excess shedding and over production of sebum. The added Pramoxine provides temporary but immediate itch relief.</p>
<p>Uses A medicated shampoo for the temporary relief of itching and scratching on dogs, cats and horses with dermatological conditions responsive to pramoxine.</p>			<p>Backing our Promise</p>
<p>Directions for use Wet the hair/coat with warm water and apply a sufficient amount of shampoo to create a rich lather. Massage medicated shampoo into wet hair/coat, lather freely. Allow the product to remain on the hair/coat for 5 - 10 minutes, then rinse thoroughly with clean water. May be used initially 2-3 times a week for 4 weeks then reducing to once a week or as directed by your veterinarian. Follow with pramoxine creme rinse if desired or towel dry pet thoroughly in a well-ventilated area.</p>			<p>The Strawfield Pets Promise to you is that we support all of your pet's needs. If you have questions or need help please contact us.</p>
<p>Warnings For topical use on animals only. Avoid contact with eyes and mucous membranes. If eye contact occurs, rinse thoroughly with water and consult a veterinarian. If undue skin irritation develops or increases, discontinue use and consult a veterinarian. Keep out of reach of children.</p>			<p>strawfieldpets.com bark@strawfieldpets.com /strawfieldpets</p>
<p>Storage Store in a cool dry place. Do not use past expiration date. The expiration date is printed on the bottom of the bottle.</p>	<p>OTHER INGREDIENTS: Water, Ammonium Lauryl Sulfate, Sodium Laureth Sulfate, Cocamidopropyl Betaine, Phenoxyethanol, Polyquaternium-7, Fragrance, Sodium Chloride, Yellow #5, Blue #1, Safflower Oil, Oatmeal Extract.</p>	 <p>X002EMEB17 Anti Itch Dog Shampoo for Veterinary Treatment, USA (Rev. 01/16) New</p>	
<p>FOR DOGS, CATS & HORSES</p>	<p>16 FLUID OUNCES (474 mL)</p>	<p>MADE IN THE USA OF US & IMPORTED INGREDIENTS Manufactured for: Strawfield Pets 2801 South 35th St Phoenix, AZ 85034</p>	

STRAWFIELD PETS ANTI-ITCH MEDICATED WITH PRAMOXINE HYDROCHLORIDE

pramoxine hydrochloride shampoo

Product Information			
Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:86127-102

Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	1 g in 100 mL	
Inactive Ingredients				
	Ingredient Name	Strength		
	WATER (UNII: 059QF0KO0R)			
	AMMONIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)			
	SODIUM LAURETH SULFATE (UNII: BPV390UAP0)			
	COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)			
	PHENOXYETHANOL (UNII: HIE492ZZ3T)			
	POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600 KD) (UNII: 0L414VCS5Y)			
	SODIUM CHLORIDE (UNII: 451W47IQ8X)			
	FD&C YELLOW NO. 5 (UNII: I753WB2F1M)			
	FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
	SAFFLOWER OIL (UNII: 65UEH262IS)			
	OATMEAL (UNII: 8PI54V663Y)			
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86127-102-16	474 mL in 1 BOTTLE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		03/20/2023		

Labeler - NEXTMUNE AB (352950223)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Veterinary Services LLC		619511483	manufacture, api manufacture

Revised: 3/2023

NEXTMUNE AB