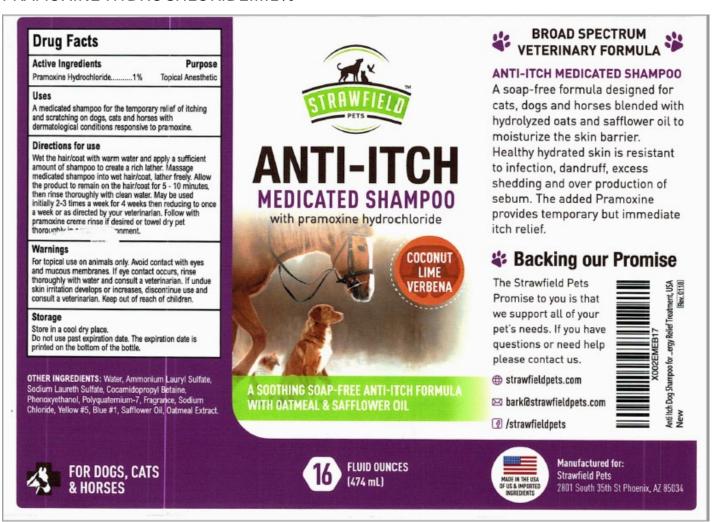
STRAWFIELD PETS ANTI-ITCH MEDICATED WITH PRAMOXINE HYDROCHLORIDE- pramoxine hydrochloride shampoo NEXTMUNE AB

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%



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 Ac	ımin i	stration

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: 50CF3011KX)	
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	
		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