PRAMOXINE HC- pramoxine hydrochloride, hydrocortisone spray Butler Animal Health Supply, LLC dba Covetrus North America

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.

Pramoxine HC Spray

ACTIVE INGREDIENTS: Hydrocortisone 1%, pramoxine hydrochloride 1%.

INACTIVE INGREDIENTS: Propylene glycol, water, SD alcohol 40B, glycerin, PEG-75 lanolin, hydrolyzed oats, benzyl alcohol.

PROPERTIES: Pramoxine HC anti-itch spray is a non-stinging formula to help provide relief from itching caused by insect bites, hot spots and other minor skin irritations. Pramoxine hydrochloride is a mild numbing agent. Hydrocortisone, lanolin and oatmeal soothe irritated skin.

INDICATIONS: For use on dogs, cats, or horses only. For the temporary relief of pruritus and skin irritations.

DIRECTIONS FOR USE: Shake well before use. Apply on dry fur 1-3 times per day for 2-3 weeks or as directed by your veterinarian. Part the fur and spray directly on the affected area(s) of the skin. Gently smooth product on to the skin to ensure full coverage. Do not allow the animal to lick the treated area.

CAUTIONS: For external use on dogs, cats, and horses only. Avoid contact with the eyes. If eye contact occurs, rinse thoroughly and consult your veterinarian. If skin irritation occurs or increases, discontinue use and consult with your veterinarian. Wash hands after use.

STORAGE: Store at room temperature. Do not freeze.

Distributed by:

Covetrus North America

400 Metro Place North

Dublin, OH 43017

covetrus.com

Questions? (855) 724-3461

PRINCIPAL DISPLAY PANEL - 8 OUNCE (237 mL) Bottle

NDC: 11695-7220-1

Pramoxine HC

Anti-itch Spray

Hydrocortisone 1%

pramoxine hydrochloride 1%

Soothing spray for

dogs, cats, and horses

For animal use only

Example 2 IKeep out of reach of children

ISHAKE WELL BEFORE USE

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Reorder #035204

Questions? (855) 724-3461

AH-035204-02 REV: 0120



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F40910D-US 18-01-v2

PRAMOXINE HC

pramoxine hydrochloride, hydrocortisone spray

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:11695-7220
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Route of Administration TOPICAL

Active Ingredient/Active Moiety

receive ingredient/receive violety				
Ingredient Name	Basis of Strength	Strength		
PRAMO XINE HYDRO CHLO RIDE (UNII: 88 AYB8 67L5) (PRAMO XINE - UNII: 068 X8 4E 056)	PRAMO XINE HYDRO CHLO RIDE	10 mg in 1 mL		
HYDROCORTISONE (UNII: WI4X0 X7BPJ) (HYDROCORTISONE - UNII:WI4X0 X7BPJ)	HYDROCORTISONE	10 mg in 1 mL		

Inactive Ingredients			
Strength			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:11695-7220-1	237 mL in 1 BOTTLE, SPRAY		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
unapproved drug other		04/27/2020			

Labeler - Butler Animal Health Supply, LLC dba Covetrus North America (603750329)

Registrant - Ceva Sante Animale (261126049)

Revised: 4/2020 Butler Animal Health Supply, LLC dba Covetrus North America