PRAMOXINE ANTI ITCH- pramoxine hydrochloride shampoo Davis Manufacturing and Packaging Inc

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 Anti-Itch Shampoo

Davis Pramoxine Anti-ItchTM Shampoo helps to provide rapid, temporary relief from pruritis caused by a variety of dermatologic conditions. The safe, fast acting formula contains 1% Pramoxine Hydrochloride which acts as an effective topical agent to aid in alleviating itching and discomfort. Colloidal Oatmeal and moisture-rich emollients condition the skin and help prevent future dryness and flaking while Omega-6 fatty acids provide dermal nourishing. Davis Pramoxine Anti-Itch Shampoo is gentle enough for frequent use and leaves the coat with a healthy shine and pleasant scent.

Environment Friendly

MADE IN THE USA

Davis Manufacturing

541 Proctor Avenue

Atlanta/Scottdale, GA 30079

www.davismfg.com

800-292-2424

Active Ingredients: Pramoxine Hydrochloride 1.0%

Inactive Ingredients: Purified Water, Cetyl Alcohol, Cetearyl Alcohol & Ceterimenium Bromide, Modified Acrylic Polymer, Germaben II, Cationic Guar Gum, Colloidal Oatmeal, Triethenolamine, Herbal Fragrance, FD&C Yellow #5, Chocolate Dye

DIRECTIONS FOR USE

Wet coat thoroughly with warm water. Apply shampoo to head ears, then lather. Do not get shampoo into eyes or nose. Repeat procedure with neck, chest, middle and hindquarters, finishing with legs. Allow shampoo to be absorbed for 5 to 10 minutes then rinse thoroughly. May be used as often as necessary or as directed by a veterinarian. For optimal results, use in conjunction with Davis Pramoxine Anti-Itch TM Creme Rinse. For added benefit between baths, apply Pramoxine Anti-Itch TM Spray to localized areas.

If contact with eyes or nose occurs, rinse thoroughly. If irritation or redness persist or increases, discontinue use and consult a veterinarian.

For External Use Only

Keep Out of Reach of Children

Davis Veterinary Products Pramoxine Anti-Itch TM Shampoo With 1% Pramoxine Hydrochloride For Dogs, Cats, Puppies and Kittens Anti-pruritic formula alleviates scratching and flaking associated with seborrhea dermatitis and other skin disorders

12 Fl. Oz. (355 ml)

Davis Pramoxine Anti-Itch[™] Shampoo helps to provide rapid, temporary relief from pruritis caused by a variety of dermatologic conditions. The safe, fast-acting formula contains 1% Pramoxine Hydrochloride which acts as an effective topical agent to aid In alleviating itching and discomfort. Colloidal Oatmeal and moisture-rich emollients condition the skin and help prevent future dryness and flaking while Omega-6 fatty acids provide dermal renourishing. Davis Pramoxine Anti-Itch Shampoo is gentle enough for frequent use and leaves the coat with a healthy shine and pleasant scent.



Anti-pruritic formula alleviates scratching and flaking associated with seborrheic dermatitis and other skin disorders

MADE IN THE USA 00 Product No. PSH12 Rev. 1218

Davis Manufacturing 541 Proctor Avenue Scottdale, GA 30079 (Atlanta) www.davismfg.com

12 Fl. Oz. (355 ml)

Active Ingredient: Pramoxine Hydrochloride 1%

Inactive Ingredients: Purified Water, Ammonium Lauryl Sulfate, Acrylates Copolymer, Propylene Glycol, Cocomidopropyl Betaine, Colloidal Oatmeal, Aloe Vera, Proprietary Fragrance Blend, Pearling Agent, D&C Green #5 Dye, Methylchloroisothiazolinone (and) Methylisothiazolinone

DIRECTIONS FOR USE

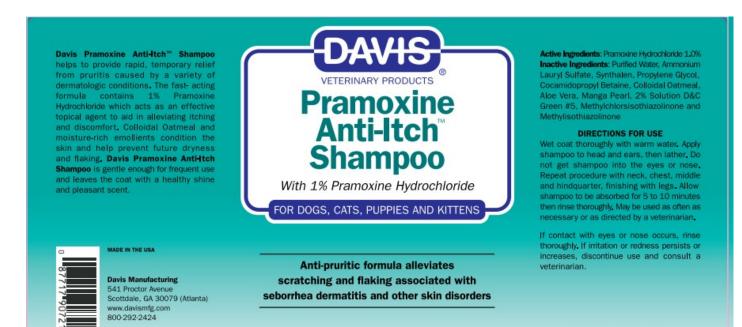
Wet coat thoroughly with warm water. Apply shampoo to head and ears, then lather. Do not get shampoo into the eyes or nose. Repeat procedure with neck, chest, middle and hindquarter, finishing with legs. Allow shampoo to be absorbed for 5 to 10 minutes then rinse thoroughly. May be used as often as necessary or as directed by a veterinarian.

If contact with eyes or nose occurs, rinse thoroughly. If irritation or redness persists or increases, discontinue use and consult a veterinarian.

> For External Use Only **Keep Out of Reach** of Children and Pets

Davis Veterinary Products Pramoxine Anti-Itch TM Shampoo With 1% Pramoxine Hydrochloride For Dogs, Cats, Puppies and Kittens Anti-pruritic formula alleviates scratching and flaking associated with seborrhea dermititis and other skin disorders

1 Gallon (3.785 Liters)



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PRAMOXINE ANTI ITCH

Product No. PSHG Rev. 0617

pramoxine hydrochloride shampoo

Product Information Product Type OTC ANIMAL DRUG Item Code (Source) NDC:62570-101 Route of Administration TOPICAL Vertical Source Vertical Source

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
PRAMO XINE HYDRO CHLO RIDE (UNII: 88 AYB867L5) (PRAMO XINE - UNII:068 X84E056)	PRAMOXINE HYDROCHLORIDE	1 g in 100 g			

Inactive Ingredients					
Ingredient Name					
WATER (UNII: 059QF0KO0R)					
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)					
AMMONIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)					
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)					
COCAMIDO PROPYL BETAINE (UNII: 50CF3011KX)					
OATMEAL (UNII: 8PI54V663Y)					
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)					
FD&C YELLOW NO.5 (UNII: I753WB2F1M)					
METHYLCHLOROISOTHIAZOLINONE/METHYLISOTHIAZOLINONE MIXTURE (UNII: 1509QS218W)					
Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		

Marketing Category	Application Number or Monograph Citation	n Marketing Start Date	Marketing End Date		
Marketing Information					
2 NDC:62570-101-01	3785 g in 1 BOTTLE				
1 NDC:62570-101-12	355 g in 1 BOTTLE				

Labeler - Davis Manufacturing and Packaging Inc (106680523)

Registrant - Vanessa Solis (106680523)

Establishment

Name	Address	ID/FEI	Business Operations
Davis Manufacturing and Packaging Inc		106680523	api manufacture

Revised: 11/2019

Davis Manufacturing and Packaging Inc