PROSORIA ANTI-ITCH MOISTURIZER- pramoxine hydrochloride lotion
Nuvothera, Inc.

Prosoria Anti-Itch Scalp Moisturizer

Drug Facts

Active ingredient

Pramoxine HCL 1%

Purpose

External analgesic

Use

for the temporary relief of itching associated with minor skin irritations

Warnings

For external use only

When using this product avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.

Stop use and consult a doctor if

- the condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

- adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily
- children under 2 years of age: consult a doctor

Inactive ingredients

Water, White Petrolatum, Glycerin, PEG-100 Stearate, Glyceryl Stearate SE, Stearic Acid, Copaifera Coriacea Resin Oil, Tetrahydrodiferuloylmethane, Cetyl Alcohol, Stearyl Alcohol, Phenoxyethanol, Vitamin E (Tocopheryl acetate), Xanthan Gum, Sodium Citrate, Disodium EDTA.

Questions?

Visit www.prosoria.com or call toll-free 1-833-776-7483 Mon – Fri, 8am – 5pm CT.

Distributed by Nuvothera, Inc.
Fort Worth, Texas 76104

PRINCIPAL DISPLAY PANEL - 90 mL Bottle Label

moisturizes
relieves itching

prosoriä

anti-itch
moisturizer

Pramoxine Hydrochloride 1%

external analgesic

3 FL OZ (90mL)

PROSORIA ANTI-ITCH MOISTURIZER

pramoxine hydrochloride lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71573-120
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Pramoxine Hydrochloride (UNII: 88AYB867L5) (Pramoxine - UNII:068X84E056)	Pramoxine Hydrochloride	0.9 g in 90 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Cetyl alcohol (UNII: 936JST6JCN)	
COPAIFERA OFFICINALIS RESIN (UNII: 1VH544O5AT)	
Tetrahydrodiferuloylmethane (UNII: 00U0645U03)	
Glyceryl Stearate SE (UNII: FCZ5MH785I)	
PEG-100 STEARATE (UNII: YD01N1999R)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Edetate Disodium Anhydrous (UNII: 8NLQ36F6MM)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
Stearic Acid (UNII: 4ELV7Z65AP)	
Glycerin (UNII: PDC6A3C0OX)	
Stearyl Alcohol (UNII: 2KR89I4H1Y)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
Xanthan Gum (UNII: TTV12P4NEE)	

Product Characteristics

Color	WHITE	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71573-120-11	90 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph drug	M015	04/01/2022	

Labeler - Nuvothera, Inc. (080499864)

Establishment

Name	Address	ID/FEI	Business Operations
Quality CDMO		117658386	MANUFACTURE(71573-120)

Revised: 1/2024 Nuvothera, Inc.