DERMEND MOISTURIZING ANTI-ITCH- pramoxine hydrochloride lotion
Ferndale Laboratories, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

DerMend Moisturizing Anti-Itch Lotion

Active ingredient

Pramoxine HCl 1% w/w

Purpose

external analgesic

Use

for the temporary relief of itching associated with minor skin irritations

Warnings

For external use only.

Avoid contact with the eyes.

Stop use and ask a doctor if

- conditions 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, seek medical attention or contact a Poison Cotrol Center right away.

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

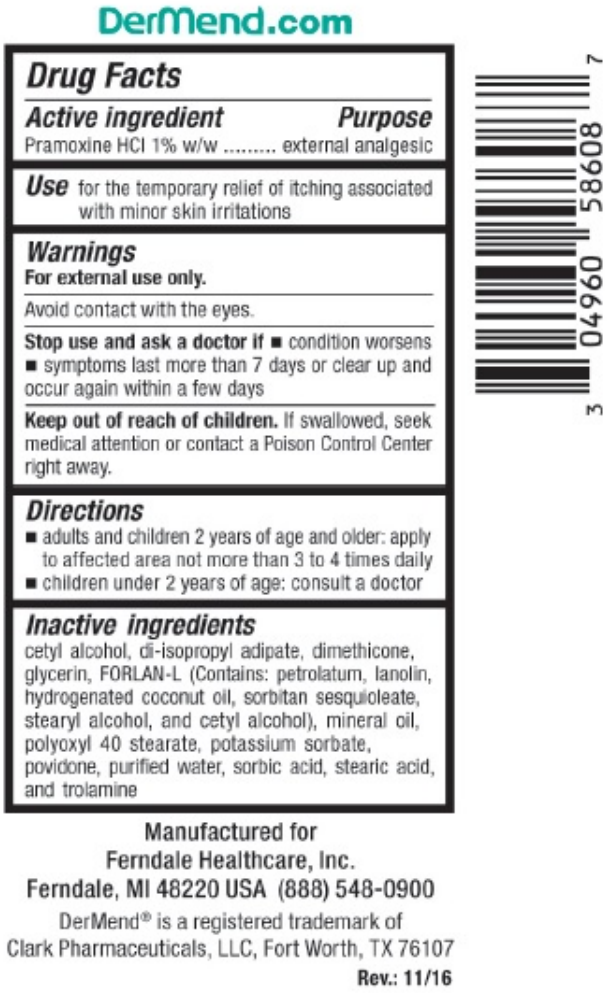
Inactive ingredients

cetyl alcohol, di-isopropyl adipate, dimethicone, glycerin, FORLAN-L (Contains: petrolatum, lanolin, hydrogenated coconut oil, sorbitan sesquioleate, stearyl alcohol, and cetyl alcohol), mineral oil, polyoxyl 40 stearate, potassium sorbate, povidone, purified water, sorbic acid, stearic acid, and trolamine

Package Label

NDC 0496-0586-08

8oz (237mL)



DERMEND MOISTURIZING ANTI-ITCH

pramoxine hydrochloride lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0496-0586
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	10 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIISOPROPYL ADIPATE (UNII: P7E6YFV72X)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERIN (UNII: PDC6A3C0OX)	
PETROLATUM (UNII: 4T6H12BN9U)	

LANOLIN (UNII: 7EV65EAW6H)	
HYDROGENATED COCONUT OIL (UNII: JY81OXM1OM)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYOXYL 40 STEARATE (UNII: 13A4J4NH9I)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
POVIDONE (UNII: FZ989GH94E)	
WATER (UNII: 059QF0KO0R)	
SORBIC ACID (UNII: X045WJ989B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0496-0586-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/01/2017	

Labeler - Ferndale Laboratories, Inc. (005320536)

Establishment

Name	Address	ID/FEI	Business Operations
Ferndale Laboratories, Inc.		005320536	manufacture(0496-0586)

Revised: 2/2017 Ferndale Laboratories, Inc.