PRAX- 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.

Prax® Lotion (Pramoxine HCl 1%)

Active Ingredient

pramoxine HCl 1% w/w

Purpose

local anesthetic

Use

for the temporary relief of discomfort and itch in the perianal area

Warnings

For external use only.

Do not

- exceed the recommended daily dosage unless directed by a doctor
- put this product into the rectum by using fingers or any mechanical device or applicator

Stop use and ask a doctor if

- condition worsens
- symptoms do not improve within 7 days
- allergic reactions develop to ingredients in this product
- symptom being treated does not subside or if redness, irritation, swelling, pain, bleeding, or other symptoms develop or increase

Keep out of reach of children.

If swallowed, seek medical attention or contact a Poison Control Center right away.

Directions

- Shake well before use.
- When practical, cleanse the affected area with mild soap and warm water and rinse thoroughly.
- Adults and children 12 years of age and older: apply to affected area up to 5 times daily.
- Children under 12 years of age: consult a doctor.

Inactive Ingredients

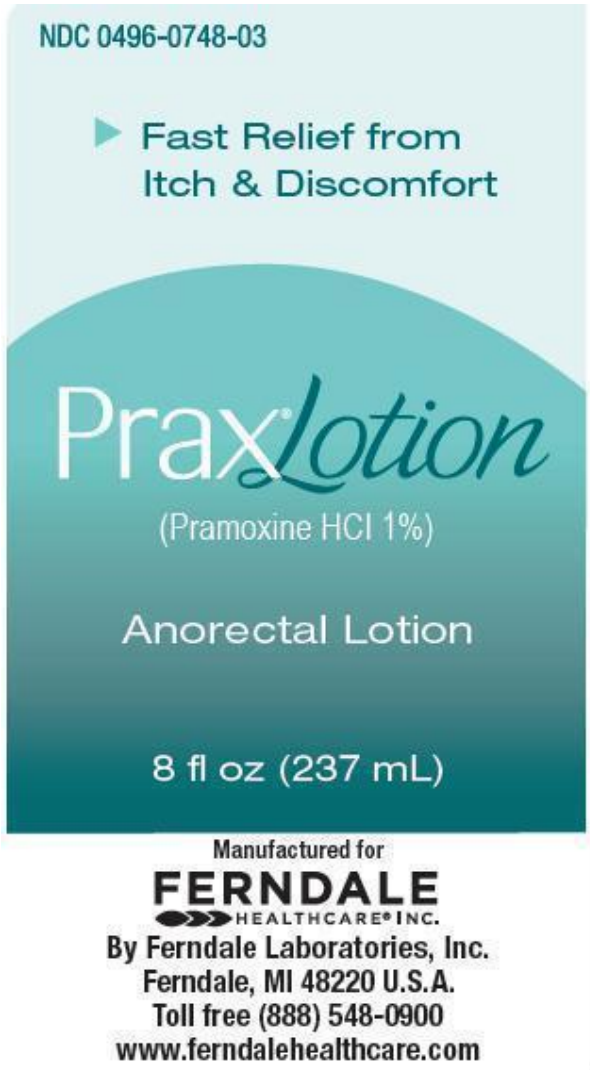
cetyl alcohol, di-isopropyl adipate, dimethicone, glycerin, FORLAN-L (Contains: petrolatum, lanolin,

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

Manufactured for
Ferndale Healthcare® Inc.
By Ferndale Laboratories, Inc.
Ferndale, MI 48220 U.S.A.
Toll Free (888) 548-0900
www.ferndalehealthcare.com

8 fl oz (237 mL) NDC 0496-0748-03



PRAX
pramoxine hydrochloride lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0496-0748
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:0496-0748-03	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2012	
2	NDC:0496-0748-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2012	
3	NDC:0496-0748-15	15 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	04/01/2012	

Labeler - Ferndale Laboratories, Inc. (005320536)

Establishment

Name	Address	ID/FEI	Business Operations
Ferndale Laboratories, Inc.		005320536	manufacture(0496-0748)