SARNA - pramoxine hydrochloride lotion
Physicians Total Care, 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.

Drug Facts

Active ingredient

Pramoxine hydrochloride 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 the eyes.

Stop use and ask a doctor if

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

Caution -- Do not use in the eyes or nose. Not for prolonged use. Do not apply to large areas of the body. If redness, irritation, swelling, or pain persists or increases, discontinue use unless directed by a physician.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- To open, squeeze cap tightly and turn pump counter-clockwise.

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**.**

Other Information

Side effects may be reported to 1-888-438-7426

Inactive ingredients

benzyl alcohol, carbomer 940, cetyl alcohol, dimethicone, glyceryl stearate, isopropyl myristate, PEG-8 stearate, PEG-100 stearate, petrolatum, purified water, sodium hydroxide, stearic acid

Find more about Sarna!

Stiefel Laboratories, Inc.

Research Triangle Park, NC 27709

www.sarna-skincare.com

Made in Canada

A099718

Additional barcode labeling by:
Physicians Total Care, Inc.
Tulsa, Oklahoma 74146

Principal Display Panel

NDC 54868-1587-0

Sarna®

SENSITIVE

Pramoxine Hydrochloride 1%

ANTI-ITCH LOTION

Steroid-Free and Fragrance-Free

DERMATOLOGIST Recommended

- Relieves itching associated with:

DRY, SENSITIVE SKIN

ECZEMA

- Moisturizing

Net Wt. 7.5 Fl Oz. (222 mL)

A099717

SARNA
pramoxine hydrochloride lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54868-1587(NDC:0145-0630)

Route of Administration	TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
POLYOXYL 8 STEARATE (UNII: 2P9L47VI5E)	
POLYOXYL 100 STEARATE (UNII: YD01N1999R)	
PETROLATUM (UNII: 4T6H12BN9U)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54868-1587-0	222 mL in 1 BOTTLE, PUMP		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/28/2008	

Labeler - Physicians Total Care, Inc. (194123980)

Establishment

Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel(54868-1587)

Revised: 9/2012 Physicians Total Care, Inc.