FREDS MEDICATED ANTI ITCH- pramoxine hydrochloride, menthol cream
Weeks and Leo, 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.

Armand Medicated Anti itch Cream

Active Ingredient

Menthol 1%

Pramoxine hydrochloride 1%

Uses

for the temporary relief of pain and itching due to: minor burns, sunburn, minor cuts, scrapes, insect bites, minor skin irritations ,minor rashes due to poison ivy, poison oak, or poison sumac

Purpose

Topical anagesic

Warnings

When using this product

do not get into eyes

Keep out of reach of children

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

Other Information

store at controlled room temperature

Directions

adults and children 2 years and older: apply to affected area not more than 3 to 4 times daily

children under 2 years: consult a doctor

Adults and Children 2 years and older: Apply to affected are not more than 3 to 4 times daily.

Inactive Ingredients

aloe barbadensis (aloe vera) leaf juice, diazolidinyl urea, edetate disodium, eucalyptus oil, methylparaben, methyl salicylate, mineral oil, PPG-1 trideceth-6, propylene glycol, propylparaben, purified water, sodium acrylates copolymer, steareth-21, stearyl alcohol, tocopheryl acetate, trolamine, white petrolatum

Medicated anti- itch Cream

Topical analgesic

Maximum strength pain and Itch relief

FREDS MEDICATED ANTI ITCH

pramoxine hydrochloride, menthol cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11383-265
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	1 g in 100 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
STEARETH-21 (UNII: 53J3F32P58)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
SODIUM ACRYLATE (UNII: 7C98FKB43H)	
MINERAL OIL (UNII: T5L8T28FGP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
TROLAMINE (UNII: 9O3K93S3TK)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
PETROLATUM (UNII: 4T6H12BN9U)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
PPG-1 TRIDECETH-6 (UNII: 1K7417JX6Q)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	

Product Characteristics			
Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:11383-265-51	1 in 1 CARTON	04/13/2014	
1		28 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/13/2014	

Labeler - Weeks and Leo, Inc. (005290028)

Registrant - Weeks and Leo, Inc. (005290028)

Establishment

Name	Address	ID/FEI	Business Operations
Weeks & Leo, Inc.		005290028	manufacture(11383-265)

Revised: 4/2019 Weeks and Leo, Inc.