QC MEDICATED ANTI ITCH- pramoxine hydrochloride, menthol cream
Chain Drug Marketing Association

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.

QC 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

Dosage

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

Package principal panel

QC MEDICATED ANTI ITCH

pramoxine hydrochloride, menthol cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63868-959
Route of Administration	TOPICAL		

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

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
TROLAMINE (UNII: 9O3K93S3TK)	
PETROLATUM (UNII: 4T6H12BN9U)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
STEARETH-21 (UNII: 53J3F32P58)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	

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

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:63868-959-01	1 in 1 CARTON	12/07/2020	
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	12/07/2020	

Labeler - Chain Drug Marketing Association (011920774)

Registrant - Weeks & Leo Co., Inc. (005290028)

Establishment

Name	Address	ID/FEI	Business Operations
WEEKS & LEO COMPANY, INC.		005290028	manufacture(63868-959)

Revised: 12/2020 Chain Drug Marketing Association