# SELECT BRAND ANTI-ITCH- menthol and pramoxine hydrochloride cream Select Brand

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.

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#### **Select Brand Anti-Itch**

**Drug Facts** 

# Active ingredients

Menthol 1%

Pramoxine hydrochloride 1%

# **Purpose**

Topical analgesic

#### Uses

for 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

# **Warnings**

# For external use only

# When using this product

do not get into eyes

#### Stop use and ask a doctor if

- condition gets worse
- symptoms last more than 7 days or clear up and occur again within a few days

#### Keep out of reach of children.

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

#### Directions

adults and children 2 years and older: apply to affected area not more than 3 or 4 times daily children under 2 years: consult a doctor

#### Other Information

• store at controlled room temperature

# **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

#### PRINCIPAL DISPLAY PANEL

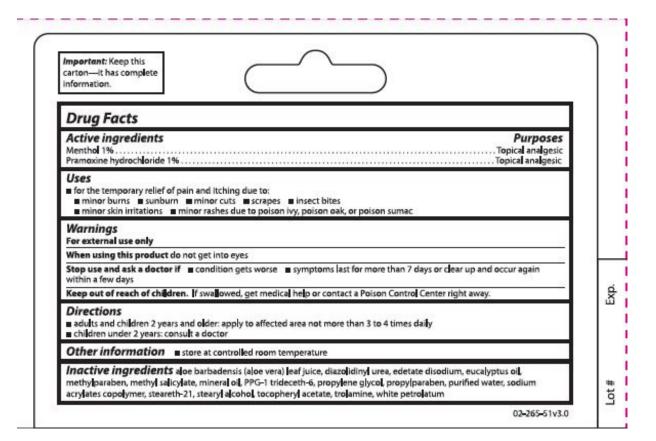
Select Brand Medicated Anti-Itch Cream

Maximum Relief

Topical Analgesic

Net wt 1 oz (28.3 g)





# SELECT BRAND ANTI-ITCH

menthol and pramoxine hydrochloride cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:15127-721
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
II <b>PRAMO XINE HYDROCHLORIDE</b> (UNII 88 AYB867L5) (PRAMO XINE - UNII 068 X84F056).	PRAMO XINE HYDRO CHLO RIDE	.1 g in 10 g	
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10 EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10 EIP3A)	MENTHOL, UNSPECIFIED FORM	.1 g in 10 g	

Inactive Ingredients			
Ingredient Name	Strength		
PROPYLPARABEN (UNII: Z8IX2SC1OH)			
WATER (UNII: 059QF0KO0R)			
METHYL SALICYLATE (UNII: LAV5U5022Y)			
SODIUM ACRYLATE (UNII: 7C98FKB43H)			
EDETATE DISO DIUM (UNII: 7FLD91C86K)			
METHYLPARABEN (UNII: A2I8C7HI9T)			
PPG-1 TRIDECETH-6 (UNII: 1K7417JX6Q)			
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)			

ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
MINERAL O IL (UNII: T5L8T28FGP)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
TROLAMINE (UNII: 9O3K93S3TK)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PETROLATUM (UNII: 4T6H12BN9U)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:15127-721-01	1 in 1 CARTON	0 1/0 3/20 14		
1		28.3 g in 1 TUBE			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/03/2012	

# Labeler - Select Brand (043562370)

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

Establishment				
Name	Address	ID/FEI	Business Operations	
Weeks & Leo Co., Inc.		005290028	label(15127-721), manufacture(15127-721), pack(15127-721)	

Revised: 1/2015 Select Brand