ANTI-ITCH- menthol and pramoxine hydrochloride cream
Dolgencorp, 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.

Anti-Itch

Active ingredients

Menthol 1%

Pramoxine hydrochloride 1%

Purpose

Anti-itch, Pain relief

Uses

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

Warnings

For external use only

Do not use on
- deep or puncture wounds
- animals bites
- serious burns
- large areas of the body

When using this product
- do not get into eyes or nose
- not for prolonged use

Stop use and ask a doctor if
- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days
- if redness, irritation, swelling or pain persists or increases

Keep out of reach of children.

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

Directions

adults and children 2 years and older: apply to affected area up to 3 or 4 times daily

children under 2 years: consult a doctor

Inactive ingredients

aloe vera (aloe barbadensis) leaf juice, diazolidinyl urea, disodium EDTA, eucalyptol, iodopropynyl

butylcarbamate, methyl salicylate, mineral oil (parraffinum liquidum), petrolatum, PPG-1 trideceth-6, propylene glycol, sodium acrylates copolymer, steareth-21, stearyl alcohol, thymol, tocopheryl acetate (vitamin E), triethanolamine, water

Other information

- store at room temperature
- for lot no. and exp. date, see crimp of tube or see box

PRINCIPAL DISPLAY PANEL

ANTI-ITCH CREAM

NET WT 1 OZ (28 g)

ANTI-ITCH

menthol and pramoxine hydrochloride cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55910-407
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**
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
EUCALYPTOL (UNII: RV6J6604TK)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
PPG-1 TRIDECETH-6 (UNII: 1K7417JX6Q)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARETH-21 (UNII: 53J3F32P58)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
THYMOL (UNII: 3J50XA376E)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	

WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-407-03	28 g in 1 TUBE; Type 0: Not a Combination Product	06/30/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/30/2016	

Labeler - Dolgencorp, Inc. (068331990)

Registrant - Anicare Pharmaceuticals Pvt. Ltd (916837425)

Establishment

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(55910-407)

Revised: 7/2016 Dolgencorp, Inc.