BUDPAK MEDICATED ANTI ITCH- camphor (synthetic) and menthol cream
Budpak 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.

Active Ingredients

Camphor 1%
Menthol 1%

Purpose

External anti-infective and anesthetic

Anti itch pain relief

Uses

For the temporary relief of pain and itching associated with:
- minor skin irritation
- allergic itches
- rashes
- hives
- minor burns
- insect bites
- poison ivy
- poison oak
- poison sumac

Warnings

For external use only

Do not use on children under 2 years of age.
- avoid contact with eyes
- do not apply to open wound or damaged skin.

Stop use and ask a doctor
- if condition worsens
- symptoms persist for 7 days or clear up and occur again within a few days.

Keep out of reach of children.

In case of accidental ingestion, get medical help or contact a Poison Control Center right away.

Directions
- For children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily.
- For children under 2 years of age: consult a physician.

Other information
- Store at controlled room temperature 15ºC to 30ºC (59ºF to 86ºF)
- Lot No. & Exp. Date: see crimp of tube.

Inactive ingredients

Purified Water, Petrolatum, Cetearyl Alcohol, Glycerin, Mineral Oil, Steareth-21, Glyceryl Stearate, Steareth-2, Alcohol, Carbomer, Triethanolamine, Methylparaben, Propylparaben, Aloe barbadensis leaf

juice, Vitamin E.

PRINCIPAL DISPLAY PANEL

Budpak Medicated Anti-Itch Cream

Camphor 1%

Menthol 1%

NET WT 1 OZ (28 g)

BUDPAK MEDICATED ANTI ITCH

camphor and menthol cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:27293-027

Route of Administration	TOPICAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	0.01 g in 1 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.01 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PETROLATUM (UNII: 4T6H12BN9U)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERIN (UNII: PDC6A3C0OX)	
MINERAL OIL (UNII: T5L8T28FGP)	
STEARETH-21 (UNII: 53J3F32P58)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
STEARETH-2 (UNII: V56DFE46J5)	
ALCOHOL (UNII: 3K9958V90M)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
TROLAMINE (UNII: 9O3K93S3TK)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:27293-027-01	1 in 1 BOX		
1	NDC:27293-027-28	28 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/17/2012	

Labeler - Budpak Inc. (183224849)

Registrant - Anicare Pharmaceuticals Pvt. Ltd (916837425)

Establishment

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(27293-027)