BUDPACK FEMININE ANTI-ITCH- benzocaine benzalkonium chloride 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.

Drug Facts

Active Ingredient

Benzocaine 5%

Benzalkonium Chloride .13%

Purpose

External analgesic

Uses

- temporarily relieves itching

Warnings

For external use only

Avoid contact with eyes

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

Do not apply over large areas of the body

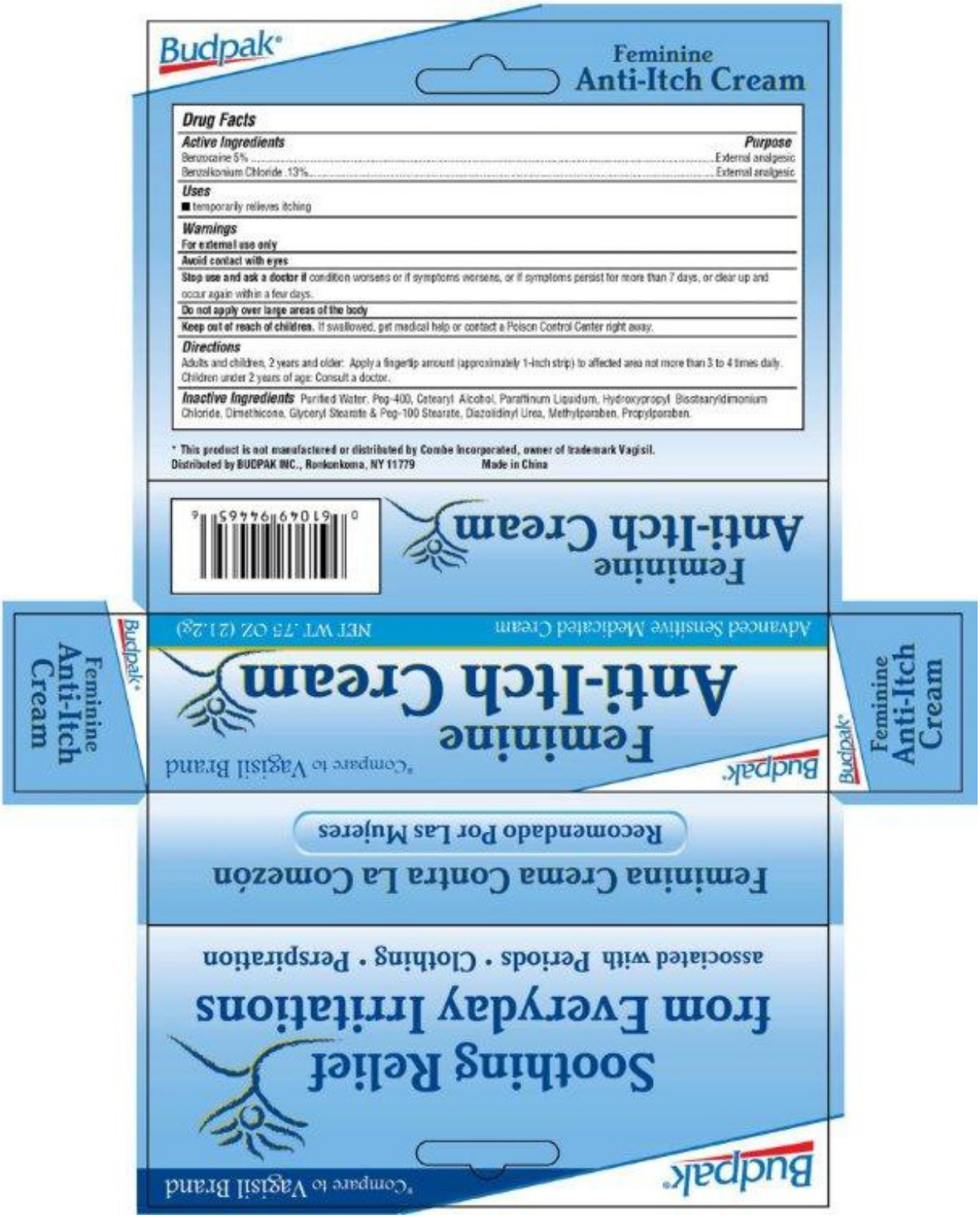
Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away

Directions

Adults and children 2 years of age and older: Apply a fingertip amount (approximately 1-inch strip) to affected area not more than 3 to 4 times daily. Children under 2 years of age: Consult a doctor

Inactive Ingredients Purified water, Peg-400, Cetearyl Alcohol, Paraffinum Liquidum, Hydroxpropyl Bisstearyldimonium Chloride, Dimethicone, Glyceryl Stearate & Peg-100 Stearate, Diaziolidinyl Urea, Methyparaben, Propylparaben

Package Label



BUDPACK FEMININE ANTI-ITCH

benzocaine benzalkonium chloride cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:27293-020

Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	5 g in 100 g
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	130 mg in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
MINERAL OIL (UNII: T5L8T28FGP)	
HYDROXYPROPYL BISSTEARYLDIMONIUM CHLORIDE (UNII: OVB1E9X12I)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:27293-020-01	1 in 1 BOX		
1	NDC:27293-020-21	21 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/21/2012	

Labeler - Budpak Inc. (183224849)

Establishment

Name	Address	ID/FEI	Business Operations
Ausmetics Daily Chemicals (Guangzhou) Co. Ltd.		529836561	manufacture

Revised: 5/2012 Budpak Inc.