

BUDPAK FEMININE ANTI-ITCH- benzocaine and resorcinol 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

Benzocaine 5%

Resorcinol 2%

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 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 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

Other information

- Store at room temperature 15°C to 30°C (59°F to 86°F).
- Lot No. Exp. Date: see crimp of the tube.

Inactive Ingredients

Purified water, cetyl alcohol, glyceryl stearate, PEG-100 stearate, mineral oil, isopropyl palmitate, aloe barbadensis leaf juice, alpha tocopherol acetate, corn oil, cholecalciferol, methyl paraben, isopropyl myristate, sodium sulfite, trolamine, trisodium HEDTA, vitamin A palmitate, carbomer homopolymer type c.

PRINCIPAL DISPLAY PANEL

Budpak Feminine Anti-Itch Cream

Benzocaine 5%

Resorcinol 2%

External analgesic

NET WT 0.75 OZ (21.2 g)

Budpak[®]

*Compare to Vagisil[®] Brand

Soothing Relief from Everyday Irritations

associated with Periods • Clothing • Perspiration

Feminina Crema Contra La Comezón

Recomendado Por Las Mujeres

Feminine
Anti-Itch
Cream

Budpak[®]

Feminine Anti-Itch Cream

*Compare to Vagisil[®] Brand

Advanced Sensitive Medicated Cream

NET WT .75 OZ (21.2g)

Budpak[®]

Feminine
Anti-Itch
Cream

Feminine Anti-Itch Cream



* This product is not manufactured or distributed by Combe Incorporated, owner of trademark Vagisil
Distributed by BUDPAK INC., Ronkonkoma, NY 11779
Made in India
Code No.: MH/DRUGS/KC-313

Drug Facts

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Feminine
Anti-Itch Cream

Budpak[®]

BUDPAK FEMININE ANTI-ITCH

benzocaine and resorcinol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:27293-022
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	0.05 g in 1 g
RESORCINOL (UNII: YUL4LO94HK) (RESORCINOL - UNII:YUL4LO94HK)	RESORCINOL	0.02 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
MINERAL OIL (UNII: T5L8T28FGP)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CORN OIL (UNII: 8470G57WFM)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
SODIUM SULFITE (UNII: VTK01UQK3G)	
TROLAMINE (UNII: 9O3K93S3TK)	
TRISODIUM HEDTA (UNII: K3E0U7O8KI)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
CARBOMER HOMO POLYMER TYPE C (UNII: 4Q93RCW27E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:27293-022-01	1 in 1 BOX		
1	NDC:27293-022-21	21.2 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/10/2013	

Labeler - Budpak Inc. (183224849)

Registrant - Anicare Pharmaceuticals Pvt. Ltd (916837425)

Establishment

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(27293-022)

