

BUDPAK FIRST AID- lidocaine hcl and phenol 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

Lidocaine HCl 0.5%

Phenol 0.5%

Purpose

Topical Anesthetic

Antiseptic

Uses

- first aid to help prevent the risk of skin infection in minor cuts, scrapes, or burns.

Warnings

For external use only

Do not use in eyes, do not apply over large areas of the body. In case of deep puncture wounds or serious burns, consult a doctor.

Stop use and ask a doctor if redness, irritation, swelling, or pain persists or increases or if infection develops.

Keep out of reach of children.

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

Directions

- Clean the affected area. Apply a small amount of this product (an amount equal to the surface area of the tip of a finger) on the area 1 to 3 times daily. May be covered with sterile bandage.

Other Information

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

Inactive Ingredients

Purified Water, Mineral Oil, Petrolatum, Cetearyl Alcohol, Glyceryl Stearate, Propylene Glycol, Stearic Acid, Methylparaben, Sorbitan Stearate, Polysorbate 60, Propylparaben, .

PRINCIPAL DISPLAY PANEL

Budpak First Aid Cream

Lidocaine HCl 0.5%

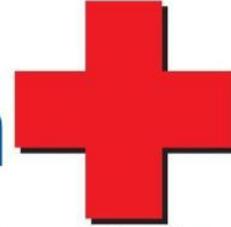
Phenol 0.5%

NET WT 1 OZ (28 g)

Budpak®

Compare to the active ingredients of
White Cross Labs®

First Aid Cream



ANTI-BACTERIAL / ANTISEPTIC CREAM

For minor burns, cuts, small wounds, scratches and abrasions

Lucha Contra la Infección, No Irritante, No Grasosa.

Crema de Primeros Auxilios



CREMA ANTIBACTERIAL/ANTISÉPTICA

Fights Infection, Non Irritating, Non Greasy.

First Aid Cream



ANTI-BACTERIAL / ANTISEPTIC CREAM

NET WT
1 OZ (28g)

Budpak®
First Aid Cream
ANTI-BACTERIAL / ANTISEPTIC CREAM

Budpak®
First Aid Cream
ANTI-BACTERIAL / ANTISEPTIC CREAM

First Aid Cream



ANTI-BACTERIAL / ANTISEPTIC CREAM



This product is not manufactured or distributed by American White Cross, owner of the trademark White Cross®.
Distributed by BUDPAK INC., Ronkonkoma, NY 11779
Code No. MHDRUGSKD-313
Made in India

Drug Facts

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Budpak®
First Aid Cream
ANTI-BACTERIAL / ANTISEPTIC CREAM

Budpak®

BUDPAK FIRST AID

lidocaine hcl and phenol cream

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:27293-016

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98P200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	0.005 g in 1 g
PHENOL (UNII: 339NCG44TV) (PHENOL - UNII:339NCG44TV)	PHENOL	0.005 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
METHYL PARABEN (UNII: A218C7H9T)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:27293-016-01	1 in 1 BOX		
1	NDC:27293-016-28	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	06/12/2013	

Labeler - Budpak Inc. (183224849)

Registrant - Anicare Pharmaceuticals Pvt. Ltd (916837425)

Establishment

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(27293-016)