FIRST AID- lidocaine hcl and phenol cream
Universal Distribution Center LLC

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.

First Aid Cream

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

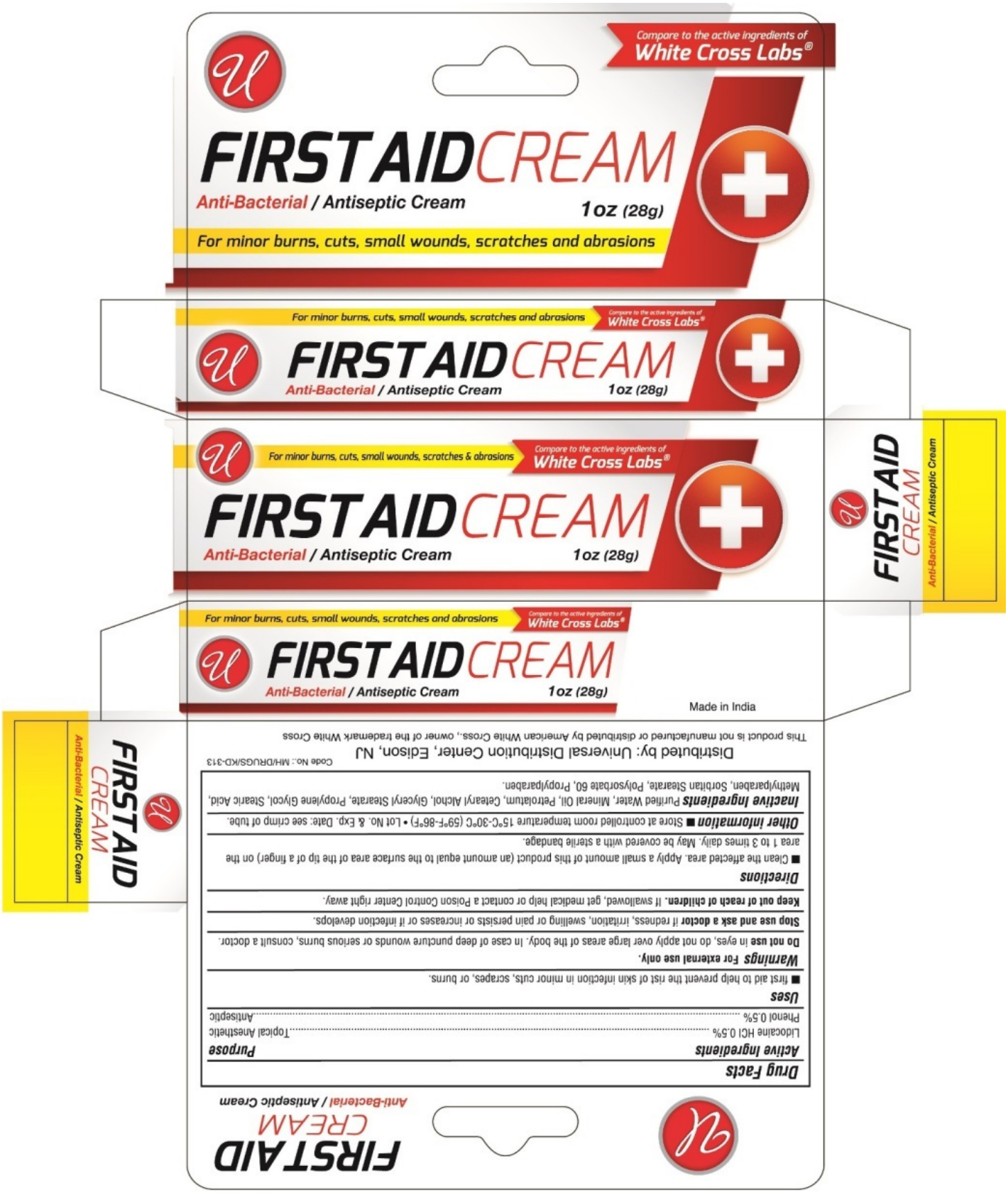
- Store at controlled room temperature 15ºC to 30ºC (59ºF to 86ºF).
- Lot No. & Exp. Date: see crimp of tube.

Inactive Ingredients

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

PRINCIPAL DISPLAY PANEL

First Aid Cream
NET WT 1 OZ (28 g)



FIRST AID

lidocaine hcl and phenol cream

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52000-027
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	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)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52000-027-37	1 in 1 CARTON	08/04/2016	
1	NDC:52000-027-39	28 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	08/04/2016	

Labeler - Universal Distribution Center LLC (019180459)

Registrant - Anicare Pharmaceuticals Pvt. Ltd (916837425)

Establishment

Name	Address	ID/FEI	Business Operations

Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(52000-027)