MAKESENSE FIRST AID- lidocaine hydrochloride phenol cream Cherry Hill Sales Co

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 ingredients

Lidocaine HCl 0.5%

Phenol 0.5%

Purpose

Topical Analgesic

Antiseptic

Uses

■ for the temporary relief of pain associated with minor cuts, scrapes or minor burns ■ first aid to help prevent the risk of skin infection in minor cuts, scrapes or minor burns

Warnings

For external use only

Do not use

■ in eyes ■ over large areas of the body ■ with a bandage

Stop use and consult a doctor if

■ in cases of deep or puncture wounds, animal bites or serious burns ■ if condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product ■ if redness, irritation, swelling, pain or other symptoms develop or increase

Keep out of reach of children

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

Directions

■ Cleanse affected area ■ Apply a small amount of this product (an amount equal to the surface of a finger) on the area 1 to 3 times daily

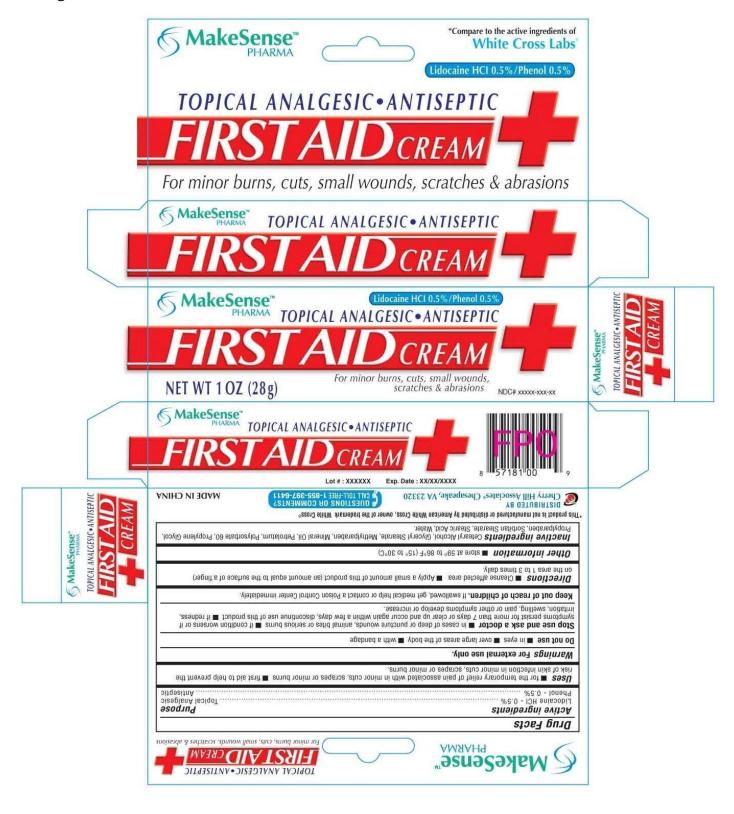
Other Information

■ store at room temperature 59 to 86F (15 to 30C) ■ see carton or tube crimp for lot number and expiration date

Inactive ingredients

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

Package Label



MAKESENSE FIRST AID

lidocaine hydrochloride phenol cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69020-210	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
LIDO CAINE HYDRO CHLO RIDE ANHYDRO US (UNII: EC2CNF7XFP) (LIDO CAINE - UNII:98 PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	0.5 g in 100 g			
PHENOL (UNII: 339NCG44TV) (PHENOL - UNII:339NCG44TV)	PHENOL	0.5 g in 100 g			

Inactive Ingredients		
Ingredient Name	Strength	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)		
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)		
METHYLPARABEN (UNII: A218 C7HI9 T)		
MINERAL OIL (UNII: T5L8T28FGP)		
PETROLATUM (UNII: 4T6H12BN9U)		
POLYSORBATE 20 (UNII: 7T1F30V5YH)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		
SORBITAN MONOSTEARATE (UNII: NVZ4I0 H58 X)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
WATER (UNII: 059QF0KO0R)		

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69020-210-28	28 g in 1 TUBE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	07/31/2014		

Labeler - Cherry Hill Sales Co (145959768)

Revised: 8/2014 Cherry Hill Sales Co