EXTRA STRENGTH NATURALLY HL WARMING ICE- lidocaine hcl cream
ridge properties

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.

Directions: Test skin to sensitivity prior to procedure. Apply generously to skin prior to and/or during procedure as needed for pain. Discontinue use if sensitivity occures. Not for use on face.

Warning - Keep out of reach of children - For external use only - Avoid contact with the eyes

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Purpose:
Topical Anesthetic

Uses: **Temporarily relieves pain**

Active ingredients:

Lidocaine HCL 4%

Inactive Ingredients:

Aloe Vera, Bee Wax, Coco Butter, (BTMS 50 – A Natural Extract Of The Colza Seed) Oils Of Grape seed, Olive, Black Pepper, Wintergreen, & Eucalyptus

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EXTRA STRENGTH NATURALLY HL WARMING ICE

lidocaine hcl cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69804-036
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	40 mg in 1000 mg

Inactive Ingredients

Ingredient Name	Strength
BEHENTRIMONIUM METHOSULFATE (UNII: 5SHP745C61)	50 mg in 1000 mg
BLACK PEPPER OIL (UNII: U17J84S19Z)	40 mg in 1000 mg
GRAPE SEED OIL (UNII: 930MLC8XGG)	120 mg in 1000 mg
EUCALYPTUS OIL (UNII: 2R04ONI662)	40 mg in 1000 mg
OLIVE OIL (UNII: 6UYK2W1W1E)	120 mg in 1000 mg
WHITE WAX (UNII: 7G1J5DA97F)	40 mg in 1000 mg
COCOA BUTTER (UNII: 512OYT1CRR)	25 mg in 1000 mg
ALOE VERA WHOLE (UNII: KIZ4X2EHYX)	525 mg in 1000 mg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69804-036-06	14200 mg in 1 JAR; Type 0: Not a Combination Product	02/09/2017	
2	NDC:69804-036-05	28500 mg in 1 JAR; Type 0: Not a Combination Product	02/09/2017	
3	NDC:69804-036-02	56700 mg in 1 JAR; Type 0: Not a Combination Product	02/09/2017	
4	NDC:69804-036-03	113400 mg in 1 JAR; Type 0: Not a Combination Product	02/09/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	02/09/2017	

Labeler - ridge properties (029478762)

Establishment

Name	Address	ID/FEI	Business Operations
ridge properties		029478762	manufacture(69804-036)

Revised: 2/2017 ridge properties