

NATURALLY HL EXTRA STRENGTH NUMBING- 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 Affected area as needed for pain. Discontinue use if sensitivity occurs. 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:

Water, Witch Hazel,
Kava kava, Organic
Alcohol, Propolis,
Yarrow, Nutmeg,
Copaiba Balsam, BTMS
50 (A natural extract of
the Colza Seed)

FDA Registered NDC# 69804-012-06	Uses: Temporarily relieves pain	Directions: Test skin to sensitivity prior to procedure. Apply generously to Affected area as needed for pain. Discontinue use if sensitivity occurs. Not for use on face.	Stop use and ask a doctor if - Skin becomes irritated - Condition worsens or symptoms last longer than 7 days - Symptoms clear up then reoccur within a few days	Other information: This product was manufactured by Pain Relief Naturally. For contact info please visit WWW.NATURALLYHL.COM	Inactive Ingredients: Water, Witch Hazel, Kava kava, Organic Alcohol, Propolis, Yarrow, Nutmeg, Copaiba Balsam, BTMS 50 (A natural extract of the Colza Seed)
Drug Facts: For professional use only	Do Not Use if you have any known allergy to any of the ingredients in this product. Discontinue use and seek medical attention should any occur	1/2 Oz Balm		Warning - Keep out of reach of children - For external use only - Avoid contact with the eyes	
<i>Active ingredients:</i> Lidocaine HCL 4% <i>Purpose:</i> Topical Anesthetic					

NATURALLY HL EXTRA STRENGTH NUMBING

lidocaine hcl cream

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:69804-012

Route of Administration	TOPICAL
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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
PROPOLIS WAX (UNII: 6Y8XYV2NOF)	40 mg in 1000 mg
BEHENTRIMONIUM METHOSULFATE (UNII: 5SHP745C61)	120 mg in 1000 mg
PIPER METHYSTICUM WHOLE (UNII: 3P306S300W)	190 mg in 1000 mg
ACHILLEA MILLEFOLIUM OIL (UNII: 97P5D0WG43)	60 mg in 1000 mg
COPAIBA OIL (UNII: 64VX45Y68N)	90 mg in 1000 mg
NUTMEG OIL (UNII: Z1CLM48948)	60 mg in 1000 mg
WITCH HAZEL (UNII: 101I4J0U34)	440 mg in 1000 mg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69804-012-02	56700 mg in 1 JAR; Type 0: Not a Combination Product	04/06/2016	
2	NDC:69804-012-03	113400 mg in 1 JAR; Type 0: Not a Combination Product	04/06/2016	
3	NDC:69804-012-05	28500 mg in 1 JAR; Type 0: Not a Combination Product	04/06/2016	
4	NDC:69804-012-06	14200 mg in 1 JAR; Type 0: Not a Combination Product	04/06/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/06/2016	

Labeler - Ridge Properties (029478762)

Establishment

Name	Address	ID/FEI	Business Operations
Ridge properties		029478762	manufacture(69804-012)