

NATURALLY HL EXTRA STRENGTH BURN NUMBING- lidocaine liquid

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.

Inactive Ingredients:

Water, Witch Hazel,

Kava kava, Organic

Alcohol, Yarrow,

Nutmeg, Copaiba Balsam

Purpose:

Topical Anesthetic

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


Uses: Temporarily relieves pain

Active ingredients:

Lidocaine HCL 4%

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

FDA Registered NDC# 69804-011-08	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, Yarrow, Nutmeg, Copaiba Balsam
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 Spray		Warning - Keep out of reach of children - For external use only - Avoid contact with the eyes	
Active ingredients: Lidocaine HCL 4% Purpose: Topical Anesthetic					

NATURALLY HL EXTRA STRENGTH BURN NUMBING

lidocaine liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69804-011
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
NUTMEG OIL (UNII: Z1CLM48948)	75 mg in 1000 mg
PIPER METHYSTICUM WHOLE (UNII: 3P306S300W)	200 mg in 1000 mg
WITCH HAZEL (UNII: 101I4J0U34)	550 mg in 1000 mg
COPAIBA OIL (UNII: 64VX45Y68N)	100 mg in 1000 mg
ACHILLEA MILLEFOLIUM OIL (UNII: 97P5D0WG43)	75 mg in 1000 mg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69804-011-01	56700 mg in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/06/2016	
2	NDC:69804-011-04	113400 mg in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/06/2016	
3	NDC:69804-011-07	28500 mg in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/06/2016	
4	NDC:69804-011-08	14200 mg in 1 BOTTLE, SPRAY; 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(69804-011)

