

EXTRA STRENGTH NUMBING GEL- lidocaine hcl gel

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 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, Aloe Vera, Witch Hazel, Konjac Root, Pickling Lime, (Pheonip - A Natural Preservative)

FDA Registered NDC # 69804-021-11	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	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.	2 Oz Gel		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, Aloe Vera, Witch Hazel, Konjac Root, Pickling Lime, (Pheonip - A Natural Preservative)
Active Ingredients: Lidocaine HCL 4%	Purpose: Topical Anesthetic						
Drug Facts: For professional use only	Uses: Temporarily relieves pain						

EXTRA STRENGTH NUMBING GEL

lidocaine hcl gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69804-021
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
WITCH HAZEL (UNII: 10114J0U34)	315 mg in 1000 mg
PHENOXYETHANOL (UNII: HIE492ZZ3T)	5 mg in 1000 mg
AMORPHOPHALLUS KONJAC ROOT (UNII: F7KU2UY3HE)	110 mg in 1000 mg
CALCIUM HYDROXIDE (UNII: PF5DZW74VN)	5 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:69804-021-09	14200 mg in 1 JAR; Type 0: Not a Combination Product	01/13/2017	
2	NDC:69804-021-10	28500 mg in 1 JAR; Type 0: Not a Combination Product	01/13/2017	
3	NDC:69804-021-11	56700 mg in 1 JAR; Type 0: Not a Combination Product	01/13/2017	
4	NDC:69804-021-12	113400 mg in 1 JAR; Type 0: Not a Combination Product	01/13/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/13/2017	

Labeler - Ridge Properties (029478762)

Establishment

Name	Address	ID/FEI	Business Operations
Ridge Properties		029478762	manufacture(69804-021)

Revised: 1/2017

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