NUMBIFY SMOOTH- lidocaine hel 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.

Warning: KEEP OUT OF REACH OF CHILDREN. FOR EXTERNAL USE ONLY. NOT FOR USE AROUND THE EYES. IF INGESTED SEEK MEDICAL HELP OR CALL A POISON CONTROL CENTER IMMEDIATELY.

Stop use and ask a doctor if skin becomes irritated, condition worsens, symptoms last longer than 7 days or if symptoms clear up and then return within a few days.

Purpose: Topical anesthetic

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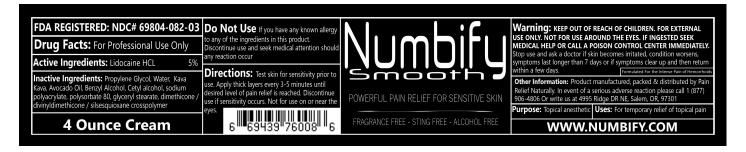
Active Ingredients: Lidocaine HCL

5%

Uses: For temporary relief of topical pain

Inactive Ingredients: Propylene Glycol, Water, Kava Kava, Avocado Oil, Benzyl Alcohol, Cetyl alcohol, sodium polyacrylate, polysorbate 80, glyceryl stearate, dimethicone / divinyldimethicone / silsesquioxane crosspolymer

Directions: Test skin for sensitivity prior to use. Apply thick layers every 3-5 minutes until desired level of pain relief is reached. Discontinue use if sensitivity occurs. Not for use on or near the eyes.



NUMBIFY SMOOTH lidocaine hcl cream **Product Information** Product Type HUMAN OTC DRUG Item Code (Source) NDC:69804-082 TOPICAL Route of Administration **Active Ingredient/Active Moiety Ingredient Name Basis of Strength** Strength LIDOCAINE HYDROCHLORIDE LIDO CAINE HYDRO CHLO RIDE (UNII: V13007Z41A) (LIDO CAINE -50 mg UNII:98PI200987) **ANHYDROUS** in 1000 mg

Inactive Ingredients				
Ingredient Name	Strength			
AVOCADO O IL (UNII: 6 VNO72PFC1)	90 mg in 1000 mg			
BENZYL ALCOHOL (UNII: LKG8494WBH)	10 mg in 1000 mg			
WATER (UNII: 059QF0KO0R)	350 mg in 1000 mg			
PIPER METHYSTICUM ROOT (UNII: BOW48C81XP)	7 mg in 1000 mg			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	403 mg in 1000 mg			
CETYL DIMETHICO NE/BIS-VINYLDIMETHICO NE CROSSPOLYMER (UNII: AE7QA6TW0Q)	90 mg in 1000 mg			

]	Packaging							
#	Item Code	Package Description	Marketing Start Date	Marketing End Date				
1	NDC:69804-082-05	28500 mg in 1 JAR; Type 0: Not a Combination Product	06/19/2020					
2	NDC:69804-082-02	56700 mg in 1 JAR; Type 0: Not a Combination Product	06/19/2020					
3	NDC:69804-082-03	113400 mg in 1 JAR; Type 0: Not a Combination Product	06/19/2020					

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC monograph not final	part348	06/19/2020					

Labeler - Ridge properties (029478762)

Establishment						
Name	Address	ID/FEI	Business Operations			
Ridge Properties		029478762	manufacture(69804-082)			

Revised: 6/2020 Ridge properties