NUMBIFY SMOOTH- 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.

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.

Inactive Ingredients: Propylene Glycol, Water, Kava Kava, Acrylates C10-30 alkyl acrylate crosspolymer, Benzyl Alcohol

Purpose: Topical anesthetic

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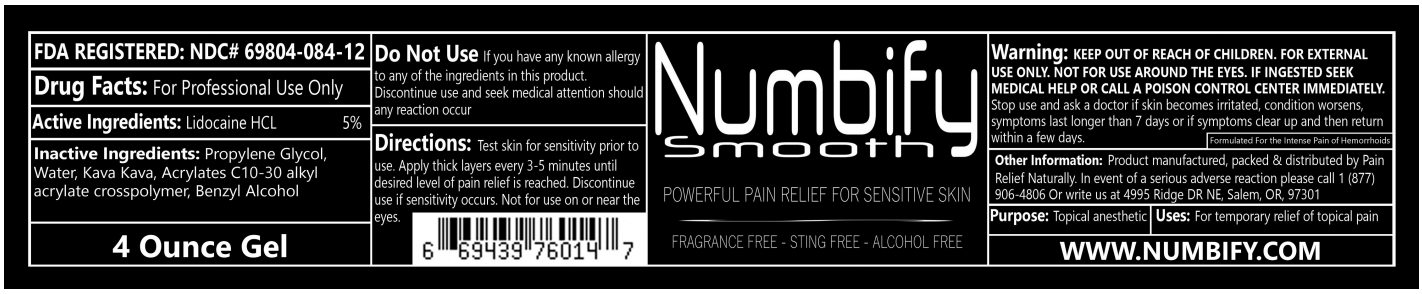
Stop use and ask a doctor if skin becomes irritated, condition worsens, symptoms last longer than 7 days or if symptoms clear up and then return within a few days.

Active Ingredients: Lidocaine HCL 5%

Uses: For temporary relief of topical pain

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 gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69804-084
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	50 mg in 1000 mg

Inactive Ingredients	
Ingredient Name	**Strength**

CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	30 mg in 1000 mg
BENZYL ALCOHOL (UNII: LKG8494WBH)	10 mg in 1000 mg
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	689 mg in 1000 mg
PIPER METHYSTICUM ROOT (UNII: BOW48C81XP)	11 mg in 1000 mg
WATER (UNII: 059QF0KO0R)	210 mg in 1000 mg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69804-084-10	28500 mg in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/19/2020	
2	NDC:69804-084-11	56700 mg in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/19/2020	
3	NDC:69804-084-12	113400 mg in 1 BOTTLE, SPRAY; 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(69804-084)

Revised: 4/2020 Ridge Properties