

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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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.

| | | | |
|---|--|--|--|
| FDA REGISTERED: NDC# 69804-084-12 | 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 reaction occur |  <p>Numbify Smooth</p> <p>POWERFUL PAIN RELIEF FOR SENSITIVE SKIN</p> <p>FRAGRANCE FREE - STING FREE - ALCOHOL FREE</p> | <p>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. <small>Formulated For the Intense Pain of Hemorrhoids</small></p> <p>Other Information: Product manufactured, packed & distributed by Pain Relief Naturally. In event of a serious adverse reaction please call 1 (877) 906-4806 Or write us at 4995 Ridge DR NE, Salem, OR, 97301</p> |
| Drug Facts: For Professional Use Only | 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. | | |
| Active Ingredients: Lidocaine HCL 5% | | | |
| Inactive Ingredients: Propylene Glycol, Water, Kava Kava, Acrylates C10-30 alkyl acrylate crosspolymer, Benzyl Alcohol | | | |
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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