

SIMPLY NUMB ENDURE- lidocaine cream
Golden Touch LLC

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.

Simply Numb Endure

Active ingredient

Lidocaine 5% W/W

Purpose

Topical Anesthetic

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Uses

For the temporary relief of pain and itching

Warnings

For external use only

When using this product

- Avoid contact with the eyes
- Do not put in rectum
- Do not exceed recommended dosage unless directed by a doctor

Stop use and ask a doctor if

- allergic reaction occurs
- condition worsens or does not improve within 7 days
- Symptoms clear up and return within a few days
- rectal bleeding occurs
- redness irritation swelling pain or other symptoms develop or increase

Directions

- Adults when practical, cleanse the affected area with mild soap and warm water and rinse thoroughly
- Gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product
- Apply externally to the affected area up to 6 times daily.
- Children under 12 years of age: consult a doctor

Inactive ingredients

Aloe Barbadensis Leaf Extract, Benzyl Alcohol, Carbomer, Disodium EDTA, Glycerin, Glyceryl Monooleate, SD Alcohol 40-B, Simmondsia Chinensis (Jojoba) Seed Oil, Water

Packaging

NDC 52763-604-80

Simply Numb Endure
 Topical Anesthetic Cream Lidocaine 5%

Numbs Skin Fast



| | | | |
|--|--------------------------------------|---|--|
| Drug Facts | | Drug Facts (continued) | |
| Active Ingredient Lidocaine 5% w/w | Purpose Topical Anesthetic | When using this Product | ● avoid contact with the eyes ● do not put in rectum ● do not exceed recommended dosage unless directed by a doctor |
| Uses | For the temporary relief of pain | Stop use and ask a doctor if: | ● allergic reaction occurs ● condition worsens or does not improve within 7 days ● symptoms clear up and return within a few days ● rectal bleeding occurs ● redness, irritation, swelling, pain or other symptoms develop or increase |
| Warnings | For external use only | Keep out of the reach of children | if swallowed, get medical help or contact a Poison Control Center right away |
| Drug Facts (continued) | | Directions | |
| | | ● Adults: When practical, cleanse the affected area with mild soap and warm water and rinse thoroughly ● Gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product ● Apply externally to the affected area up to 6 times daily ● Children under 12 years of age: consult a doctor | |
| Inactive Ingredients Aloe Barbadensis Leaf Extract, Benzyl Alcohol, Carbomer, Disodium EDTA, Glycerin, Glyceryl Monooleate, SD Alcohol 40-B, Simmondsia Chinensis (Jojoba) Seed Oil, Water. | | | |

www.SimplyNumb.com 800-527-1995 Golden Touch LLC, 957 Oasis Road Benton KY 42025

SIMPLY NUMB ENDURE

lidocaine cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:52763-604 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|--------------|
| LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987) | LIDOCAINE | 5 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| BENZYL ALCOHOL (UNII: LKG8494WBH) | |
| CARBOMER HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| GLYCERYL OLEATE (UNII: 4PC054V79P) | |
| ALCOHOL (UNII: 3K9958V90M) | |
| SIMMONDSIA CHINENSIS SEED (UNII: D24K2Q1F6H) | |
| WATER (UNII: 059QF0K00R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:52763-604-80 | 480 g in 1 JAR; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part346 | 07/08/2014 | |

Labeler - Golden Touch LLC (194284147)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------|---------|-----------|------------------------|
| Golden Touch LLC | | 194284147 | manufacture(52763-604) |

Revised: 11/2015

Golden Touch LLC