LIDOCREAM 4- 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.

LidoCream 4

Active ingredient

Lidocaine 4% 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 due to

- minor burns
- minor skin irritations

Warnings

For external use only

When using this product

- Avoid contact with the eyes
- Do not use in large quantities particularly over raw surfaces or blistered areas.
- 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
- notice any unusual effects such as blurred vision, dizziness or drowsiness, difficulty in breathing, trembling, chest pain or irregular heart beat

Directions

- Adults and children 2 years and older: apply externally to the affected area not more than 3 to 4 times daily
- Children under 2 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

LidoCream 4 Numbs Skin Fast



Net Wt. 2 Oz (60g)

| Drug Facts | Drug Facts (continued) | |
|--|--|--|
| Active Ingredient Purpose | Surfaces or plistered areas and do no | |
| Lidocaine 4% w/wTopical Anesthetic Uses For the temporary relief of pain and itching due to ● minor burns ● minor skin irritations | Stop use and ask a doctor in within 7 days symptoms clear up blurred vision, dizziness or drowsin | |
| Warnings | Keep out of the reach of children | |
| For external use only | Directions • adults and children than 3 to 4 times daily • children | |
| | Inactive Ingredients Aloe Bar Glycerin, Glyceryl Monooleate, SD | |
| 3 5 2 7 6 3 4 0 1 6 0 1 | www.LidoCream.com | |

NDC 52763-401-60

| | Drug ruois (contantaca) | | | | |
|----------------------------------|--|----------------------------------|--|--|--|
| Purpose al Anesthetic | When using this Product surfaces or blistered areas do not | | ot use in large quantities particularly over raw directed by a doctor | | |
| ain and itching skin irritations | within 7 days 🔵 symptoms clear up | and return within a few days | condition worsens or does not improve notice any unusual effects such as ng, chest pain, or irregular heartbeat. | | |
| | Keep out of the reach of children right away | n if swallowed, get medical help | o or contact a Poison Control Center | | |
| | Directions • adults and children 2 years and older: apply externally to the affected area not more than 3 to 4 times daily • children under 2 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. | | | | |
| 1 | www.LidoCream.com | 800-527-1995 | Golden Touch LLC 957 Oasis Rd. Benton, KY 42025 | | |

LIDOCREAM 4

lidocaine cream

| Product Information | | | | | |
|-------------------------------------|--------------------------|--------------|---------------------------|----------|--------------|
| Product Type | HUMAN OTC DRUG | Item Code (S | ource) | NDC:5276 | 53-401 |
| Route of Administration | TOPICAL | | | | |
| | | | | | |
| Active Ingredient/Active Moi | ety | | | | |
| Ingre | edient Name | | Basis of Stre | ngth | Strength |
| LIDO CAINE (UNII: 98PI200987) (LIDO | CAINE - UNII:98PI200987) | | LIDOCAINE | 4 | 4 g in 100 g |
| | | | | | |
| Inactive Ingredients | | | | | |
| | Ingredient Name | | | | Strength |
| ALOE VERA LEAF (UNII: ZY81Z83H0) | X) | | | | |
| BENZYL ALCOHOL (UNII: LKG8494V | VBH) | | | | |
| CARBOMER HOMOPOLYMER TYPE | C (ALLYL PENTAERYTHRIT | OL CROSSLIN | KED) (UNII: 4Q93RC | CW27E) | |
| EDETATE DISO DIUM (UNII: 7FLD9 1C8 | 36K) | | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | | |
| GLYCERYL OLEATE (UNII: 4PC054V7 | 79 P) | | | | |
| ALCOHOL (UNII: 3K9958V90M) | | | | | |
| SIMMONDSIA CHINENSIS SEED (UNI | l: D24K2Q1F6H) | | | | |
| WATER (UNII: 059QF0KO0R) | | | | | |
| | | | | | |
| | | | | | |

| Packaging | | | | | |
|-----------------------|---|----------------------|--------------------|--|--|
| # Item Code | Package Description | Marketing Start Date | Marketing End Date | | |
| 1 NDC:52763-401-60 | 1 in 1 CARTON | | | | |
| 1 | 60 g in 1 TUBE; 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 | 12/0 1/20 10 | | | |
| | | | | | |

Labeler - Golden Touch LLC (194284147)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------|---------|-----------|----------------------------|
| Golden Touch LLC | | 194284147 | manufacture(52763-401) |

Revised: 11/2015

Golden Touch LLC