

SUGARDOH OUCHIE RELIEF ROLLER- lidocaine gel

Sugardoh LLC

Sugardoh Ouchie Relief Roller

Drug Facts

Active Ingredient

Lidocaine 5%w/w

Purpose

Local anesthetic

Uses

temporarily relieves pain and itching due to anorectal disorders

Warnings

When using this product

- avoid contact with eyes
- do not exceed recommended dosage unless directed by a doctor
- do not put htis product into the rectum by using fingers or any mechanical device or applicator.

Stop use and ask a doctor if

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

Keep out of reach of children.

Directions

When practical, clean area with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or soft cloth before applying.

Adults and children 12 years and older: Apply to the affected area up to 6 times a day.

Children under 12 years of age: Consult a doctor.

Other information

- Store at USP controlled room temperature 20° - 25° C (68° - 77°F)

Inactive ingredients

Alcohol Denat., Aloe Barbadensis Leaf Extract, Benzyl Alcohol, Camellia Sinensis Leaf Extract, Citral, Denatonium benzoate, Fragrance, Hexyl Cinnamal, Isopulegol, Limonene, Linalool, Menthoxyprompanediol, PVP, t-Butyl Alcohol, Water

Questions or comments

support@sugardoh.co

(737) 295-9222

Product Packaging



SUGARDOH OUCHIE RELIEF ROLLER

lidocaine gel

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:83987-001 |
| Route of Administration | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|--|-------------------|---------------|
| Ingredient Name | Basis of Strength | Strength |
| LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987) | LIDOCAINE | 50 mg in 1 mL |

| Inactive Ingredients | |
|---|----------|
| Ingredient Name | Strength |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| BENZYL ALCOHOL (UNII: LKG8494WBH) | |
| .ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I) | |
| 3-((L-MENTHYL)OXY)PROPANE-1,2-DIOL (UNII: KD6TZ2QICH) | |
| TERT-BUTYL ALCOHOL (UNII: MD83SFE959) | |
| WATER (UNII: 059QF0KO0R) | |
| DENATONIUM BENZOATE (UNII: 4YK5Z54AT2) | |
| GREEN TEA LEAF (UNII: W2ZU1RY8B0) | |
| CITRAL (UNII: T7EU0O9VPP) | |
| ISOPULEGOL (UNII: 3TH92O3BXN) | |
| POVIDONE (UNII: FZ989GH94E) | |
| ALCOHOL (UNII: 3K9958V90M) | |
| LIMONENE, (+)- (UNII: GFD7C86Q1W) | |
| LINALOOL, (+)- (UNII: F4VNO44C09) | |

| Packaging | | | | |
|-----------|------------------|--|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:83987-001-01 | 1 in 1 BOX | 02/28/2024 | |
| 1 | | 44 mL in 1 TUBE, WTH APPLICATOR; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC Monograph Drug | M015 | 02/28/2024 | |

Labeler - Sugardoh LLC (118209443)