

4 LIDOCAINE TOPICAL ANESTHETIC- lidocaine cream

RUGBY LABORATORIES

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.

4% Lidocaine Topical Anesthetic Cream

Drug Facts

Active ingredient

Active ingredient

Purpose

Topical Analgesic

Uses

temporarily relieves pain and itching due to:

- minor cuts
- minor scrapes
- sunburn
- minor skin irritations
- minor burns
- insect bites

Warnings

For external use only.

When using this product

- do not use in or near the eyes
- do not use in large quantities, particularly over raw surfaces or blistered areas.

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
- redness, irritation, swelling, pain or other symptoms begin or increase

Do not apply over large areas of the body.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- Adults and children 2 years and older: Apply externally to the affected area up to 3-4 times daily.
- Children under 2 years: Consult a doctor.

Other information

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

Inactive ingredients

aloe barbadensis leaf extract, benzyl alcohol, carbomer 940, cetyl alcohol, cholesterol, di-alpha tocopherol, glycerin, hydrogenated lecithin, isopropyl myristate, polysorbate 80, propylene glycol, purified water, stearic acid, trolamine

Questions & Comments?

1-800-645-2158

Package Labeling:



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Lidocaine 4% w/w.....Topical Analgesic

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lidocaine cream

Product Information

| | | | | |
|-------------------------------------------------------------------------------------|-------------------------------------------------|--------------------------------------------------|-----------------------------|---------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0536-1267 | |
| Route of Administration | TOPICAL | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987) | | LIDOCAINE | 40 mg in 1 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) | | | | |
| CETYL ALCOHOL (UNII: 936JST6JCN) | | | | |
| CHOLESTEROL (UNII: 97C5T2UQ7J) | | | | |
| .ALPHA.-TOCOPHEROL, DL- (UNII: 7QWA1RIO01) | | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | |
| HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N) | | | | |
| ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS) | | | | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | | | | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | | | | |
| WATER (UNII: 059QF0KO0R) | | | | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | | | | |
| TROLAMINE (UNII: 9O3K93S3TK) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0536-1267-20 | 15 g in 1 BOX; Type 0: Not a Combination Product | 04/30/2020 | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph not final | part348 | 04/30/2020 | | |

Labeler - RUGBY LABORATORIES (079246066)

Revised: 4/2020

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