

PAIN RELIEF ROLL-ON- lidocaine 4% liquid
Bionpharma Inc.

pain relief roll-on

Active ingredient

Lidocaine 4%

Purpose

Topical analgesic

Uses

For temporarily relief of pain and itching.

Warnings

For external use only.

When using this product

- use only as directed
- do not bandage tightly
- avoid contact with eyes
- do not apply to wounds or damaged skin
- do not use in large quantities, particularly over raw surfaces or blistered areas

Stop use and ask a doctor

If

- condition worsens
- symptoms persist for more than 7 days or clear up and occur again within a few days

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

Adults and children 2 years of age and older: apply to the affected area no more than 3 to 4 times daily.

Children under 2 years of age: consult a doctor.

Inactive ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Extract, Aminomethyl Propanol, C30-45 Alkyl Cetearyl Dimethicone Crosspolymer, Caprylyl Methicone, Cetearyl Alcohol, Ceteth-20 Phosphate, Dicaprylyl Phosphate, Dimethicone, Disodium EDTA, Ethylhexylglycerin, Glyceryl Stearate, Methylparaben, polysorbate 60, SD Alcohol 40, Steareth-21, Purified Water

Carton Label

*compare to the active ingredient

in Aspercreme® Odor Free

with 4 % Lidocaine

NDC 69452-393-63

a+health™

maximum strength

pain relief

roll-on

lidocaine 4% HCl/

topical analgesic

odor free

no mess applicator

- temporary relief of pain
- helps pain-affected areas

without irritation

2.5 fl oz (74mL)

with aloe



PAIN RELIEF ROLL-ON

lidocaine 4% liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:69452-393 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-----------------------------------|---------------|
| LIDOCAINE HYDROCHLORIDE (UNII: V13007Z 41A) (LIDOCAINE - UNII: 98P1200987) | LIDOCAINE HYDROCHLORIDE ANHYDROUS | 4 g in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| AMINOMETHYLPROPANOL (UNII: LU49E6626Q) | |
| WATER (UNII: 059QF0KO0R) | |
| STEARETH-21 (UNII: 53J3F32P58) | |
| ALCOHOL (UNII: 3K9958V90M) | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | |
| CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL) | |
| CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) | |
| EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM) | |
| DIHEXADECYL PHOSPHATE (UNII: 2V6E5WN99N) | |
| CETETH-20 PHOSPHATE (UNII: 921FTA1500) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | |
| HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPA.S AT 1%) (UNII: 86FQE96TZ4) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:69452-393-63 | 1 in 1 CARTON | 02/20/2023 | |
| 1 | | 74 mL in 1 BOTTLE, WITH 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 | M017 | 02/20/2023 | |

Labeler - Bionpharma Inc. (079637826)

Registrant - Bionpharma Inc. (079637826)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------|---------|-----------|---|
| Pharma Nobis, LLC | | 118564114 | manufacture(69452-393) , analysis(69452-393) , label(69452-393) , pack(69452-393) |