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

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.

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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, Dicetyl 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

- temporarary 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: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	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 not final	part348	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)

Revised: 2/2023 Bionpharma Inc.