

FAST FREEZE LIDOCAINE ROLL-ON- lidocaine hydrochloride, benzyl alcohol liquid
Natural Essentials, 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.

DRUG FACTS

ACTIVE INGREDIENTS

Lidocaine HCl 4%

Benzyl Alcohol 10%

PURPOSE

Topical Anesthetic

Topical Anesthetic

USES

Temporary relief of minor pain

WARNINGS

For external use only

FLAMMABLE:Keep away from fire or flame

DO NOT USE

- on wounds or damaged skin
- in large quantities
- with a heating pad
- if you are allergic to any ingredients of this product

WHEN USING THIS PRODUCT

- use only as directed
- avoid contact with the eyes, mucous membranes or rashes
- do not bandage tightly

STOP USE AND ASK A DOCTOR IF

- skin reactions occur, such as rash, itching, redness, irritation, pain, swelling and blistering
- conditions worsen
- symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days

IF PREGNANT OR BREAST-FEEDING, ask a health professional before use.

KEEP OUT OF REACH OF CHILDREN AND PETS. If swallowed, get medical help or contact a Poison Control Center right away.

DIRECTIONS

- Adults and children 12 years of age and over
- clean and dry affected area
- apply to affected area not more than 3 to 4 times daily children 12 years or younger ask a doctor

OTHER INFORMATION

- Avoid storing product in direct sunlight
- Protect product from excessive moisture
- Store with lid closed tightly

INACTIVE INGREDIENTS

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, Citric Acid, Deionized Water, SDA 40-B Alcohol, Tromethamine

Principal Display Panel – 89 mL Container Label

FAST FREEZE[®]

MAXIMUM STRENGTH

LIDOCAINE

ROLL-ON

UNSCENTED

- Numbing relief
- No mess, greaseless & stain-free
- Natural ingredients include Aloe
- For the temporary relief of minor aches and pains of muscles and joints; associated with backache, arthritis, strains and sprains
- Paraben Free
- Plus 10% Benzyl Alcohol

3 oz (89 mL)

FAST FREEZE

Lidocaine Roll-On

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Manufactured for:
DJO, LLC
Vista, CA 92081
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FF203PR01-Art Rev A

FAST FREEZE LIDOCAINE ROLL-ON

lidocaine hydrochloride, benzyl alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66902-235
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Lidocaine Hydrochloride (UNII: V13007Z41A) (Lidocaine - UNII:98PI200987)	Lidocaine Hydrochloride Anhydrous	40 mg in 1 mL
Benzyl Alcohol (UNII: LKG8494WBH) (Benzyl Alcohol - UNII:LKG8494WBH)	Benzyl Alcohol	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
WATER (UNII: 059QF0K00R)	
ALCOHOL (UNII: 3K9958V90M)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66902-235-03	89 mL in 1 CONTAINER; Type 0: Not a Combination Product	07/10/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/10/2020	

Labeler - Natural Essentials, Inc. (947484713)

Establishment

Name	Address	ID/FEI	Business Operations
NATURAL ESSENTIALS, INC.		947484713	MANUFACTURE(66902-235)

Revised: 7/2020

Natural Essentials, Inc.