

**FAST FREEZE LIDOCAINE- lidocaine spray**  
**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.*

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**DRUG FACTS**

**ACTIVE INGREDIENTS**

Lidocaine 4%

**PURPOSE**

Topical Anesthetic

**USES**

Temporary relief of minor pain

**WARNINGS**

For external use only

**DO NOT USE**

- In large quantities, particularly over raw surfaces or blistered areas

**WHEN USING THIS PRODUCT**

- Keep out of eyes
- Use only as directed
- do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120°F

**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

**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**

Shake well

- Adults and children over 12 years:

Apply a thin layer to affected area not more than 3 to 4 times daily

- To apply to face, spray into palm of hand and gently apply
- Children under 12 years of age, ask a doctor

**INACTIVE INGREDIENTS**

Acrylates/C10-30 Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, Chamomilla Recutita

(Matricaria) Flower Extract, Cucumis Sativus (Cucumber) Fruit Extract, Deionized Water, Diazolidinyl Urea, Dimethicone, Disodium Cocamphodipropionate, Disodium EDTA, Glycerin, Propylene Glycol, SDA 39C Alcohol, Tocopheryl Acetate, Triethanolamine.

## Principal Display Panel – 118 mL Can Label

**FAST FREEZE®**

MAXIMUM STRENGTH

**LIDOCAINE**

CONTINUOUS SPRAY

UNSCENTED

- Numbing relief
- No mess, greaseless & stain-free
- Natural ingredients include Vitamin E and Aloe
- For the temporary relief of minor aches and pains of muscles and joints; associated with backache, arthritis, strains and sprains
- Paraben Free
- Fast Drying

3 oz (89 mL)

**FAST FREEZE®** Lidocaine Continuous Spray

DRUG FACTS	
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<b>KEEP OUT OF REACH OF CHILDREN AND PETS</b> If swallowed, get medical help or contact a Poison Control Center right away.	
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Individual results may vary. Neither DJO, LLC nor any of its subsidiaries dispense medical advice. Please consult your healthcare professional for information on the courses of treatment, if any, which may be appropriate for you.

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MADE IN USA  
Manufactured for:  
DJO, LLC  
Vista, CA 92081  
©2020 DJO, LLC

4 oz (118 mL)

FF203PS01-A1 Rev A

# FAST FREEZE LIDOCAINE

lidocaine spray

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66902-225
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 mL

## Inactive Ingredients

Ingredient Name	Strength
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
MATRICARIA CHAMOMILLA FLOWERING TOP (UNII: 3VNC7T6Z02)	
CUCUMBER (UNII: YY7C30VXJT)	
WATER (UNII: 059QF0K00R)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DISODIUM COCOAMPHODIPROPIONATE (UNII: 6K8PRP397M)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALCOHOL (UNII: 3K9958V90M)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66902-225-04	118 mL in 1 CAN; 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
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NATURAL ESSENTIALS, INC.		947484713	MANUFACTURE(66902-225)
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Revised: 7/2020

Natural Essentials, Inc.