

## **FAST FREEZE- menthol gel**

### **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**

Menthol 3.5%

#### **Purpose**

Cooling Pain Relief

#### **Uses**

Temporary relief of minor aches and pains of muscles and joints associated with:

- Simple backache
- Arthritis
- Strains
- Sprains

#### **Warnings**

- **For external use only**
- Flammable
- Keep away from excessive heat or open flame

#### **Do not use**

- With heating pad or device
- With ointments, creams, sprays or liniments
- On wounds, damaged skin or irritated skin

#### **Ask a doctor before use if you**

- Have sensitive skin
- Are pregnant or breastfeeding

#### **When using this product**

- Avoid contact with eyes or mucous membranes
- Do not bandage tightly

#### **Stop use and ask a doctor if**

- Condition worsens
- Symptoms persist for more than 7 days or clear up then reoccur again within a few

days

- Irritation develops

### **Keep out of reach of children.**

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

### **Directions**

#### **Adults/Children 2 years and older:**

- Roll on the affected area not more than 3 to 4 times daily
- Shake well before use

**Children under 2 years old:** Consult a physician.

### **Other information**

- Replace cap after use
- Store in a cool, dry place

### **Inactive ingredients**

Aloe Barbadensis (Aloe Vera) Leaf Extract, Carbomer, Ilex Paraguariensis Leaf Extract, Isopropyl Alcohol, Methylparaben, Tocopherol (Vitamin E) Acetate, Triethanolamine, Water.

### **Questions?**

Call 317-228-1144 or visit [www.Bell-Horn.com](http://www.Bell-Horn.com) or [www.fastfreeze.com](http://www.fastfreeze.com)

Principal Display Panel – Bottle Label

### ***FAST FREEZE*®**

Naturally  
Cool

Pain Relieving Roll-On

Helps to relieve

- Sore muscles
- Strains & sprains
- Joint pain

- .....
- Invigorating cooling menthol
  - Greaseless & stain-free
  - Natural ingredients include  
Vitamin E, Aloe & Ilex
- .....

3 oz (89 mL)

**FAST FREEZE®** Pain Relieving Roll-On

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**MADE IN USA**

Manufactured for:  
DJO, LLC  
Vista, CA 92081  
©2012 DJO, LLC

8H-5204 Rev B

**FAST FREEZE®**

**Naturally Cool**  
**Pain Relieving Roll-On**

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**3 oz (89 mL)**

## FAST FREEZE

menthol gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66902-016
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	35 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)				
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)				
<b>WATER</b> (UNII: 059QF0KO0R)				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66902-016-05	1 g in 1 PACKET; Type 0: Not a Combination Product	01/01/2013	
2	NDC:66902-016-03	1 g in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2013	
3	NDC:66902-016-04	1 g in 1 TUBE; Type 0: Not a Combination Product	01/01/2013	
4	NDC:66902-016-16	1 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/01/2013	
5	NDC:66902-016-32	1 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/01/2013	
6	NDC:66902-016-01	1 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/01/2013	
<b>Marketing Information</b>				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part348	01/01/2013	

**Labeler** - Natural Essentials Inc. (947484713)

## Establishment

Name	Address	ID/FEI	Business Operations
Natural Essentials Inc.		947484713	MANUFACTURE(66902-016)

Revised: 11/2022

Natural Essentials Inc.