# 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 or www.fastfreeze.com

Principal Display Panel – Bottle Label

FAST FREEZE®

Naturally Cool

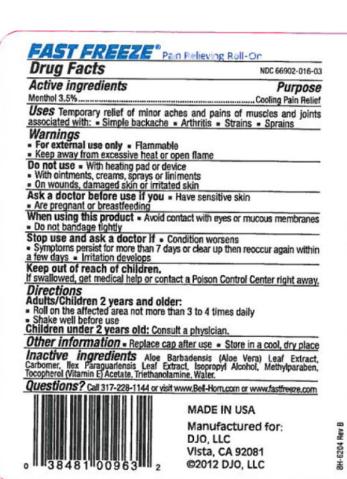
Pain Relieving Roll-On

Helps to relieve

- Sore muscles
- Strains & sprains
- Joint pain

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

3 oz (89 mL)





# Naturally Cool

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#### **FAST FREEZE**

menthol gel

# Product Information Product Type HUMAN OTC DRUG LABEL Item Code (Source) NDC:66902-016 Route of Administration TOPICAL DEA Schedule

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
MENTHOL (MENTHOL)	MENTHOL	35 mg in 1 g		

Inactive Ingredients			
Ingredient Name	Strength		
ALOE VERA LEAF			
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED)			
ILEX PARAGUARIENSIS LEAF			
ISOPROPYL ALCOHOL			
METHYLPARABEN			
.ALPHATO COPHERO L ACETATE			
TROLAMINE			
WATER			

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 1	NDC:66902-016-05	1 g in 1 PACKET			
2 1	NDC:66902-016-03	1 g in 1 BOTTLE			
3 1	NDC:66902-016-04	1 g in 1 TUBE			
4 1	NDC:66902-016-16	1 g in 1 BOTTLE, PUMP			
5 1	NDC:66902-016-32	1 g in 1 BOTTLE, PUMP			
6 1	NDC:66902-016-01	1 g in 1 BOTTLE, PUMP			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	0 1/0 1/20 13		

# Labeler - Natural Essentials Inc. (947484713)

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

Revised: 12/2012 Natural Essentials Inc.