# FAST FREEZE- menthol 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**

Menthol 10%

#### **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
- Avoid spraying in eyes
- Contents under pressure. Do not puncture or incinerate container. Do not store at temperature above 120°F (48°C)

#### 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:

- Spray 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, Ilex Paraguariensis Leaf Extract, SDA-39c Alcohol, Tocopherol (Vitamin E) Acetate, 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

Continuouse Spray

Helps to relieve

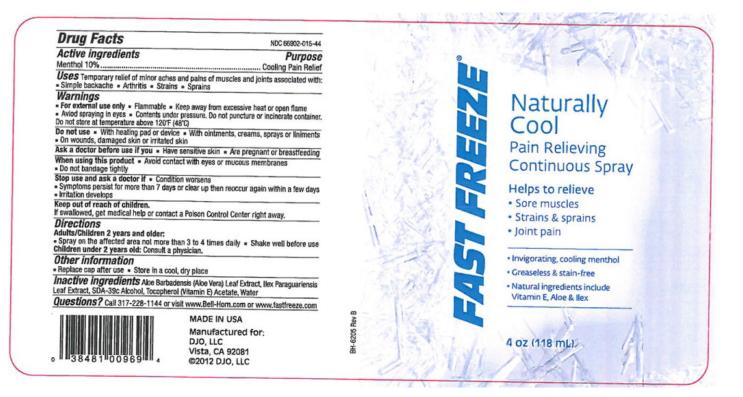
- Sore muscles
- Strains & sprains
- Joint pain

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

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4 oz (118 mL)



#### **FAST FREEZE**

menthol spray

Product Information				
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:66902-015	
Route of Administration	TOPICAL	DEA Sche dule		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
MENTHOL (MENTHOL)	MENTHOL	100 mg in 1 g		

Inactive Ingredients	
Ingredient Name	Strength
ALOE VERA LEAF	
ILEX PARAGUARIENSIS LEAF	
ISOPROPYL ALCOHOL	
.ALPHATO COPHERO L ACETATE	
WATER	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66902-015-27	1 g in 1 BOTTLE, PUMP		
2	NDC:66902-015-04	1 g in 1 BOTTLE, PUMP		
3	NDC:66902-015-44	1 g in 1 CAN		

4 NDC:66902-015-16	1 g in 1 BOTTLE, PUMP			
Marketing Information				
Marketing Category	Application Number or Monog	raph 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(66902-015)	

Revised: 12/2012 Natural Essentials Inc.