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.

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®

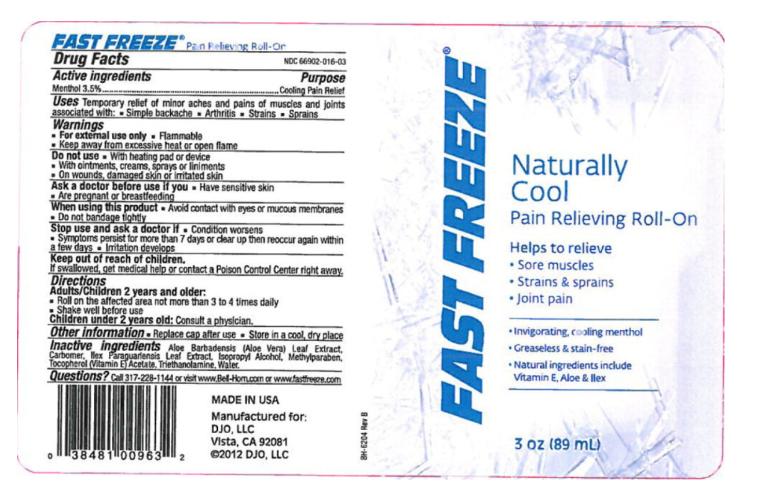
Naturally Cool

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

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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)	

.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 903K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	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	

Marketing Information			
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				
Na me	Address	ID/FEI	Business Operations	
Natural Essentials Inc.		947484713	MANUFACTURE(66902-016)	

Revised: 11/2022 Natural Essentials Inc.