

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 Barbadosis (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 & 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

BH-6204 Rev B

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: 1Q953B404F) | |
| ISOPROPYL ALCOHOL (UNII: ND2M416302) | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | |

| | |
|--|--|
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |
| 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

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

Revised: 11/2022

Natural Essentials Inc.