FAST FREEZE PAIN RELIEVING- menthol, unspecified form 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 Leaf Extract, Carbomer, dl-alpha Tocopheryl Acetate, dl-Camphor, Isopropyl Alcohol, Mate (Ilex Paraguariensis) Extract, Methylparaben, Triethanolamine, Water.

Questions?

Call 317-228-1144 or visit www.Bell-Horn.com or www.fastfreeze.com

Principal Display Panel - 89 mL Container 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

Drug Facts NDC 66902-116-03

Active ingredients **Purpose**
Menthol 3.5% ..... Cooling Pain Relief

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Questions? Call 317-228-1144 or visit www.Bell-Horn.com or www.fastfreeze.com

FPO 90%
0 38481 00963 2
0 00000 00000 0

MADE IN USA
Manufactured for:
DJO, LLC
Vista, CA 92081
©2012 DJO, LLC

BH-6204 Rev C

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)

Principal Display Panel - 120 mL Tube Label

FAST FREEZE®

Naturally
Cool
Pain Relieving Gel

Helps to relieve
- Sore muscles
- Strains & sprains
- Joint pain
- Invigorating, cooling menthol
- Greaseless & stain-free
- Natural ingredients include Vitamin E, Aloe & Ilex

Net wt. 4 oz (113 g)

FAST FREEZE®

Naturally Cool

Pain Relieving Gel

Helps to relieve

- Sore muscles
- Strains & sprains
- Joint pain

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

Net wt. 4 oz (113 g)

FAST FREEZE®

Pain Relieving Gel

Drug Facts

NDC 66902-116-04

Active ingredients **Purpose**

Menthol 3.5% ..... 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:
▪ Rub 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 Leaf Juice, Carbomer, dl-Camphor, dl-Tocopheryl Acetate, Isopropyl Alcohol, Methyl Paraben, Organic Ilex Paraguariensis Leaf Juice, Triethanolamine, Water

Questions? Call 317-228-1144 or visit www.Bell-Horn.com or www.fastfreeze.com

MADE IN USA

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

BH-6210 Rev C

0 38481 00961 8

FAST FREEZE PAIN RELIEVING

menthol, unspecified form gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:66902-116
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	33 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66902-116-03	89 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/31/2021	
2	NDC:66902-116-04	120 mL in 1 TUBE; Type 0: Not a Combination Product	10/06/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/31/2021	

Labeler - NATURAL ESSENTIALS, INC. (947484713)

Establishment

Name	Address	ID/FEI	Business Operations
NATURAL ESSENTIALS, INC.		947484713	MANUFACTURE(66902-116)

Revised: 10/2021 NATURAL ESSENTIALS, INC.