

FAST FREEZE- camphor (natural), 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

Camphor 0.2%, 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:

- 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 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, Pump Label

NEW!

BELL-HORN

FAST FREEZE®

PAIN RELIEVING GEL

FREEZES PAIN

INSTANTLY!

HELPS TO RELIEVE:

- SORE MUSCLES
- STRAINS & SPRAINS
- JOINT PAIN

(GREAT FOR ARTHRITIS)

16 oz (473 mL)

BELL-HORN FAST FREEZE
PAIN RELIEVING GEL

NEW!

BELL-HORN FAST FREEZE
PAIN RELIEVING GEL

Drug Facts

NDC 66902-000-16

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MADE IN USA
Manufactured for
DJO, LLC
Vista, CA 92081

BH-6200 Rev A

FREEZES PAIN INSTANTLY!

HELPS TO RELIEVE:
- SORE MUSCLES
- STRAINS & SPRAINS
- JOINT PAIN
(GREAT FOR ARTHRITIS)

16 oz (473 mL)

FAST FREEZE

camphor (natural), menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66902-000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	2 mg in 1 g
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:66902-000-05	1 g in 1 PACKET; Type 0: Not a Combination Product	04/01/2010	
2	NDC:66902-000-03	1 g in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2010	
3	NDC:66902-000-04	1 g in 1 TUBE; Type 0: Not a Combination Product	04/01/2010	
4	NDC:66902-000-16	1 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/01/2010	
5	NDC:66902-000-32	1 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/01/2010	
6	NDC:66902-000-01	1 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/01/2010	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/01/2010	

Labeler - Natural Essentials Inc. (947484713)

Establishment			
Name	Address	ID/FEI	Business Operations
Natural Essentials Inc.		947484713	MANUFACTURE(66902-000)