

ICY FREEZE- menthol, unspecified form 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.

Drug Facts

NDC 66902-168-40

Active ingredients

Menthol 10%

Purpose

Cooling Pain Relief

Uses

Temporary relief from minor aches and pains associated with:

- Tendonitis
- Strains
- Sprains
- Sore muscles
- Joint discomfort
- Arthritis

Warnings

- **For external use only**
- Flammable
- Keep away from excessive heat or open flame

Do not use

- With heating pad or device
- With creams, ointments, 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

- Apply to the affected area not more than 3 to 4 times daily; Rub into skin until solution vanishes

Children under 2 years old:

- Application should be supervised by an adult.

Other information

- Replace cap after use
- Store in a cool, dry place.

Inactive ingredients

Aloe Barbadosis Leaf Extract, Mate (Ilex Paraguariensis), dl-Camphor, SDA-39C Alcohol, dl-alpha Tocopheryl acetate, Purified Water.

Questions?

Call 317-689-7711

Principal Display Panel – 4 oz Can Label

THERAPEUTIC PAIN RELIEF

Greaseless and stain free with Aloe, Vitamin E and Ilex

NATURAL INGREDIENTS • SOOTHING MENTHOL • VANISHING SCENT

ICY FREEZE

COOLING PAIN RELIEF

FOR TENDONITIS, ARTHRITIS. SPRAINS AND STRAINS

FREEZES PAIN

360° CONTINUOUS SPRAY

4 FL OZ (120 mL)

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ICY-FREEZE.COM



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Paraguariensis), dl-Camphor, SDA-39C

Alcohol, dl-alpha Tocopheryl acetate,

Purified Water.

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MADE IN USA for Header Health LLC

Zionsville, Indiana 46077 TM Reg'd

85126-L

FREEZES PAIN

Therapeutic Pain Relief
Greaseless and stain free with Aloe, Vitamin E, and Ilex

NATURAL INGREDIENTS • SOOTHING MENTHOL • VANISHING SCENT

ICY FREEZE[®]

COOLING PAIN RELIEF
FOR TENDONITIS, ARTHRITIS, SPRAINS AND STRAINS

360° CONTINUOUS SPRAY

4 FL. OZ. (120 mL)

ICY FREEZE

menthol, unspecified form spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66902-168
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	89 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
ALCOHOL (UNII: 3K9958V90M)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:66902-168-40	120 mL in 1 CAN; Type 0: Not a Combination Product	05/14/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	05/14/2020		

Labeler - Natural Essentials, Inc. (947484713)

Establishment			
Name	Address	ID/FEI	Business Operations
NATURAL ESSENTIALS, INC.		947484713	MANUFACTURE(66902-168)

Revised: 5/2020

Natural Essentials, Inc.