

ICY 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.

ICY FREEZE COOLING PAIN RELIEF

Drug Facts

Active ingredient

Menthol 3.5%

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.

Non-medicinal ingredients Aloe Barbadosis Leaf Extract, Mate (Ilex Paraguariensis) Extract, dl-alpha Tocopheryl acetate, Purified Water, dl-Camphor, Carbomer, Isopropyl alcohol, Methylparaben, Triethanolamine.

MADE IN USA for Healer Health LLC

Zionsville, Indiana 46077 TM Reg'd 85140-L

ICYFREEZE.COM

Principal Display Panel - Icy Freeze 3oz Gel Pump

FREEZES PAIN

THERAPUTIC 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

GEL

4 FL OZ (120 mL)

ICY FREEZE COOLING PAIN RELIEF

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▪ 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.

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Non-medicinal ingredients

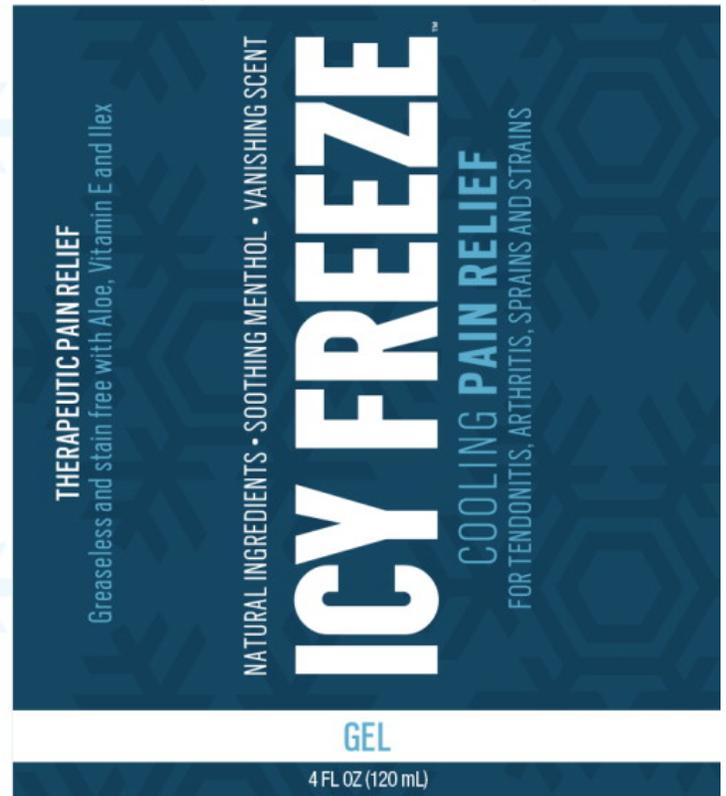
Aloe Barbadensis Leaf Extract,
Mate (Ilex Paraguariensis) Extract,
dl-alpha Tocopheryl acetate, Purified
Water, dl-Camphor, Carbomer,
Isopropyl alcohol, Methylparaben,
Triethanolamine.

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FREEZES PAIN



Principal Display Panel - Icy Freeze 3oz Roll On

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

ROLL-ON

3 FL OZ (90 mL)

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 • 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.

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Aloe Barbadensis Leaf Extract,
 Mate (Ilex Paraguariensis) Extract,
 dl-alpha Tocopheryl acetate, Purified
 Water, dl-Camphor, Carbomer,
 Isopropyl alcohol, Methylparaben,
 Triethanolamine.

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THERAPEUTIC PAIN RELIEF
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NATURAL INGREDIENTS • SOOTHING MENTHOL • VANISHING SCENT

ICY FREEZE™

COOLING PAIN RELIEF
 FOR TENDONITIS, ARTHRITIS, SPRAINS AND STRAINS

ROLL-ON

3 FL. OZ (90 mL)

ICY FREEZE

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66902-165
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 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66902-165-03	1 in 1 BOTTLE, WITH APPLICATOR	12/01/2017	
1		90 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:66902-165-04	1 in 1 BOTTLE, PUMP	12/01/2017	
2		120 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/01/2017	

Labeler - NATURAL ESSENTIALS, INC. (947484713)**Establishment**

Name	Address	ID/FEI	Business Operations
NATURAL ESSENTIALS, INC.		947484713	MANUFACTURE(66902-165)

Revised: 12/2017

NATURAL ESSENTIALS, INC.