# 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.

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# **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 Barbadensis 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)

# ICY FREEZE COOLING PAIN RELIEF

Drug Footo

**Drug Facts** 

NDC 66902-168-40

Active ingredients

Purpose ...... Cooling Pain Relief

Wenthol 10%

Uses Temporary relief from minor aches and pains associated with:

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

Warnings

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: Bub into skin until solution vanishes

Children under 2 years old: - Application should be supervised by an adult.

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Inactive ingredients

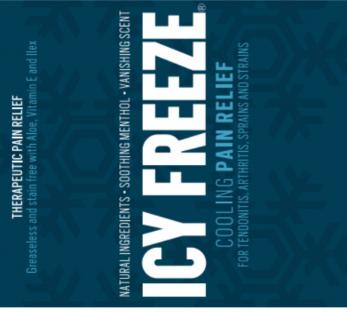
Aloe Barbadensis Leaf Extract, Mate (flex Paraguariensis), dl-Camphor, SDA-39C Alcohol, dl-alpha Tocopheryl acetate, Purified Wister.

Questions? Call 317-689-7711

MADE IN USA for Healer Health LLC Zionsville, Indiana 46077 TM Reg'd

85126-L





360° CONTINUOUS SPRAY

4 FL 0Z (120 mL)

# **ICY FREEZE**

menthol, unspecified form spray

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Pro	anct	Intor	mation

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66902-168
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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: ZY8 1Z8 3H0 X)			
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)			
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)			
ALCOHOL (UNII: 3K9958V90M)			
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)			
WATER (UNII: 059QF0KO0R)			

Pac	kaging			
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>

1 NDC:66902-168-40 1	20 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	
Marketing Category		J	9	
OTC monograph not final	• • •	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.