# RAW ICE- menthol gel Rescue Dog Health

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**

# **Active Ingredient**

Menthol 3.5%

# Purpose

Pain Reliever

#### Uses

Temporarily relieves minor pain associated with: muscle sprains, muscle strains, neck/back aches/pains, sore joints, arthritis, cramps and bruises.

# **Warnings**

For external use only. Flammable. Keep away from open flame or extreme heat. Keep out of reach of children. If swallowed get medical help or contact a poison control center right away. When using this product: Use only as directed. Avoid contact with eyes and mucous membranes. Do not apply to open wounds or damaged skin. Do not bandage tightly. Do not use with a heating pad or other ointments, creams, sprays or liniments. Do not apply to irritated skin. Wash hands thoroughly after each application. Stop use and ask a health professional if condition worsens, if symptoms persist for more than 7 days or clear up and recur again within a few days, or if irritation occurs. If pregnant or breast feeding ask a health care professional before use. Store at room temperature.

#### **Directions**

For adults and children 6 years of age and older: Shake well. Clean skin. Apply a liberal amount of gel directly on the skin over the affected area until absorbed into skin. Repeat as necessary, but not more than 4 times daily. May also be applied before or after activity. For children under 6 years of age, consult a health care professional.

#### **Inactive Ingredients**

Aloe Barbadensis, Cinnamomum Camphora (Camphor) Bark Oil, Dehydroxanthan Gum, Glycerin, Mentha Piperita (Peppermint) Oil, Organic Chamomilla Recutita (Matricaria) Flower Extract, Organic Symphytum Officinale (Comfrey), SDA 38B, Xanthan Gum

# Rescue Health, LLC

Bentonville, AR 72712

www.rawhealthintl.com Ph: 1-888-RAW-HLTH

#### **Questions or comments:**

#### **Principal Display Panel - Bottle Label**

 $RAW^{TM}$ 

**ICE** 

100% Natural Pain Relief

For arthritis, muscle and joint pain

**ROLL-ON GEL** 

3 fl OZ/89 mL

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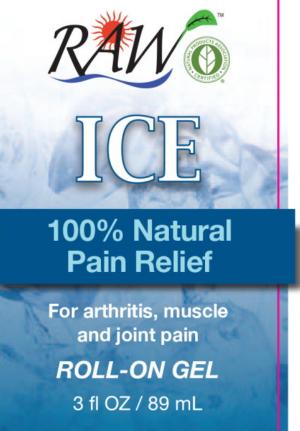
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containers are BPA Free Made in the USA No Animal Testing 100% Recyclable Container



# **Principal Display Panel - Bottle Label**

 $RAW^{TM}$ 

**ICE** 

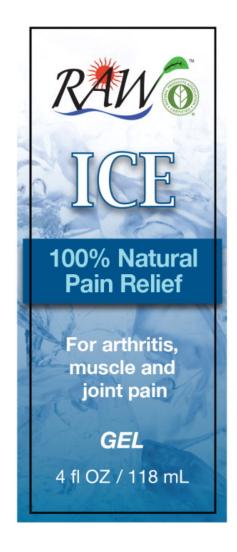
100% Natural Pain Relief

For arthritis, muscle and

#### joint pain

#### **GEL**

4 fl OZ/118 mL



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# Drug Facts (continued)

Warnings (continued)

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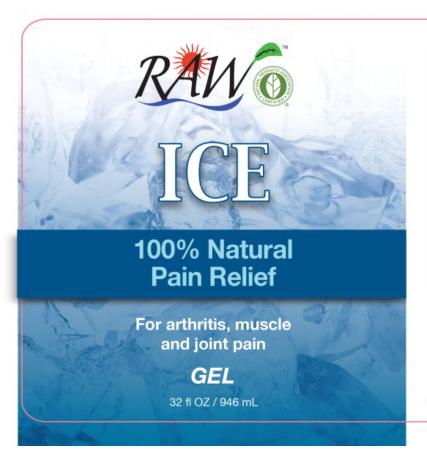
**ICE** 

100% Natural Pain Relief

For arthritis, muscle and joint pain

**GEL** 

32 fl OZ/946 mL



#### Drug Facts

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### **RAW ICE**

menthol gel

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:69381-2500

Route of Administration TOPICAL

#### **Active Ingredient/Active Moiety**

Ingredient NameBasis of StrengthStrengthmenthol (UNII: L7T10EIP3A) (menthol - UNII:L7T10EIP3A)menthol3.5 mg in 1 L

# Inactive Ingredients Ingredient Name Strength aloe vera leaf (UNII: ZY8 1Z8 3H0 X) glycerin (UNII: PDC6 A3C0 OX) peppermint oil (UNII: AV09 2KU4JH) xanthan gum (UNII: TTV12P4NEE) camphor oil (UNII: 75IZZ8 Y727) matricaria recutita (UNII: G0R4UB1ZZZ) symphytum uplandicum leaf (UNII: D05HXK6R3G)

Packaging								
7	# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>				
	NDC:69381-2500-1	0.089 L in 1 BOTTLE; Type 0: Not a Combination Product						
:	NDC:69381-2500-2	0.118 L in 1 BOTTLE; Type 0: Not a Combination Product						
:	NDC:69381-2500-3	$0.946\ L\ in\ 1BOTTLE;\ Type\ 0:\ Not\ a\ Combination\ Product$						

Marketing Information								
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date					
OTC monograph not final	part348	12/18/2014						

# Labeler - Rescue Dog Health (079558153)

# **Registrant -** Safetec of America, Inc. (874965262)

Establishment								
Name	Address	ID/FEI	Business Operations					
Safetec of America, Inc.		874965262	MANUFACTURE(69381-2500)					

Revised: 12/2014 Rescue Dog Health