RAW ICE- menthol liquid
Raw Health International, LLC

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 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 (Aloe) Leaf Gel, SDA 38B, Glycerin, Mentha Piperita (Peppermint) Oil, Xanthan Gum, Dehydroxyxanthan Gum, Cinnamomum Camphora (Camphor) Bark Oil, Organic Chamomilla Recutita (Matricaria) Flower Extract, Organic Symphytum Officinalis (Comfrey)

RAW Health International, LLC
91 Ft. Couch Road-Pittsburgh, PA 15241
www.rawhealthintl.com
Ph: 1-888-RAW-HLTH

Questions or comments:

Email us at: info@rawhealthintl.com

MSRP $14.99

PRINCIPAL DISPLAY PANEL – 3 oz. bottle

RAW
RAW HEALTH INTERNATIONAL

ICE

The All-Natural
Cooling Pain Reliever

Muscle Strains,
Joint Sprains, Neck/Back Aches,
Pains and Much More…

3 fl OZ / 89 mL

www.rawhealthintl.com
Also Try RAW-HEAT for warming pain relief

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

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ICE

The All-Natural Cooling Pain Reliever

Muscle Strains, Joint Sprains, Neck/Back Aches, Pains and Much More...

3 fl OZ / 89 mL

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RAW ICE

menthol liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55413-2500
Route of Administration	TOPICAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
menthol (UNII: L7T10EIP3A) (menthol - UNII:L7T10EIP3A)	menthol	34.79 g in 1 L

Inactive Ingredients

Ingredient Name	Strength
aloe vera leaf (UNII: ZY81Z83H0X)	
glycerin (UNII: PDC6A3C0OX)	
peppermint oil (UNII: AV092KU4JH)	
xanthan gum (UNII: TTV12P4NEE)	
camphor oil (UNII: 75IZZ8Y727)	
matricaria recutita (UNII: G0R4UBI2ZZ)	
symphytum uplandicum leaf (UNII: D05HXK6R3G)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55413-2500-1	0.089 L in 1 BOTTLE		
2	NDC:55413-2500-2	0.118 L in 1 BOTTLE		
3	NDC:55413-2500-3	0.004 L in 1 PACKET		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/15/2013	

Labeler - Raw Health International, LLC (014982454)

Registrant - Safetec of America, Inc. (874965262)

Establishment

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	MANUFACTURE(55413-2500)