

## **ROCKSAUCE ICE- menthol gel**

**NINGBO SANTE YING MEDICAL AND HEALTH DEVELOPMENT CO., LTD**

*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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**rocksauce ICE**

**RockSauce ICE**

### **Active Ingredient**

Menthol 6.0%

### **Purpose**

Topical Analgesic

### **Uses**

Provides soothing cold to sore muscles

### **Warnings**

**For external use only.**

**Avoid contact with eyes, mucous membrane or broken skin.**

### **When using this product:**

do not: heat, microwave, add to hot water or any container where heating water may cause splattering and result in burns, use in eyes or directly on mucus membrane, take by mouth or place in nostrils, apply to wounds or damaged skin.

Do not use otherwise than as directed.

### **Consult a doctor and discontinue use**

if irritation occurs.

### **Keep out of reach of children.**

In case of accidental ingestion, get medical help or call a Poison Control Center right away.

### **Directions**

Apply liberally to area of pain and massage until lotion is absorbed into the skin. Repeat 3-4 times daily. See important warnings under "When using this product". Not for children 5 years or younger. Store at 68° to 77°F (20° to 25°C).

## Inactive Ingredients

Water, Isopropyl Alcohol, Glycerin, Aloe Barbadensis Leaf Extract, Calendula Officinalis Extract, Arctium Lappa (Burdock) Root Extract, Ilex Paraguariensis Leaf Extract, Arnica Montana Flower Extract, Boswellia Carterii Resin Extract, Camellia Sinensis (Green Tea) Leaf Extract, Melissa Officinalis (Lemon Balm) Leaf Extract, Camphor, Isopropyl Myristate, Carbomer, Triethanolamine, Silica, Tocopheryl (Vitamin E) Acetate

RockSauce ICE

Net wt 2.5g

Icy cold pain relief cream

Soothies sore muscles and joints

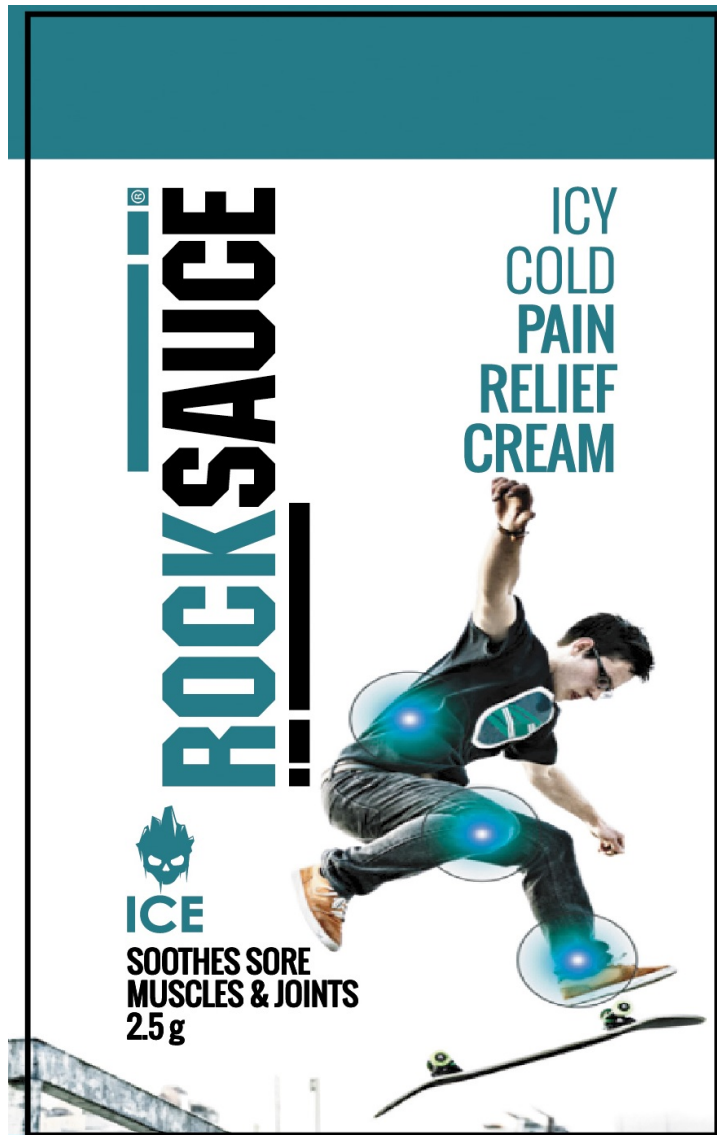
DISTRIBUTED BY:

Rocktape, Inc

questions: please contact 408-912-7625

made in china

## rock sauce chill

 <p><b>ROCKSAUCE</b> ICY COLD PAIN RELIEF CREAM</p> <p><b>ICE</b> SOOTHES SORE MUSCLES &amp; JOINTS 2.5g</p> <p>A skateboarder is shown in mid-air, performing a trick. The skateboarder's joints (shoulder, elbow, hip, knee, ankle) are highlighted with glowing blue circles, indicating the product's application area.</p>	<h3>DRUG FACTS</h3> <table border="1"><thead><tr><th>Active Ingredient</th><th>Purpose</th></tr></thead><tbody><tr><td>Menthol 6%</td><td>Topical Analgesic</td></tr></tbody></table> <p><b>Uses:</b> Provides soothing cold to sore muscles</p> <p><b>Warnings:</b> <b>For external use only.</b> Avoid contact with eyes, mucous membrane or broken skin.</p> <p><b>When using this product, do not:</b> heat, microwave, add to hot water or any container where heating water may cause splattering and result in burns, use in eyes or directly on mucus membrane, take by mouth or place in nostrils, apply to wounds or damaged skin. <b>Do not use otherwise than as directed.</b></p> <p><b>Consult a doctor and discontinue use if irritation occurs.</b></p> <p><b>Keep out of reach of children:</b> In case of accidental ingestion, get medical help or call Poison Control Center right away.</p> <p><b>Directions:</b> Apply liberally to area of pain and massage until lotion is absorbed into the skin. Repeat 3-4 times daily. See important warnings under "when using this product". Not for children 5 years or younger. Store at 68° to 77°F (20° to 25°C)</p> <p><b>Inactive Ingredients:</b> Water, Isopropyl Alcohol, Glycerin, Aloe Barbadensis Leaf Extract, Calendula Officinalis Extract, Arctium Lappa (Burdock) Root Extract, Ilex Paraguariensis Leaf Extract, Arnica Montana Flower Extract, Boswellia Carterii Resin Extract, Camellia Sinensis (Green Tea) Leaf Extract, Melissa Officinalis (Lemon Balm) Leaf Extract, Camphor, Isopropyl Myristate, Carbomer, Triethanolamine, Silica, Tocopheryl (Vitamin E) Acetate.</p> <p>Contact Info Distributed by: RockTape Inc (US) 1(408)912-7625 RockTape Inc (AUS) 08 9379 3400 Transatlantic Fitness (DE) 49(89)500 80 79</p> <p>DESIGNED IN CALIFORNIA Made in China LOT: 2458149 EXP: 01/2020</p> <p><b>NOT FOR RETAIL SALE</b>      <b>CE EHC</b></p>	Active Ingredient	Purpose	Menthol 6%	Topical Analgesic
Active Ingredient	Purpose				
Menthol 6%	Topical Analgesic				

# ROCKSAUCE ICE

menthol gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73344-101
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	6.0 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
GLYCERIN (UNII: PDC6A3C0OX)	
ARCTIUM LAPPA ROOT OIL (UNII: 55DGS3F5YG)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
MELISSA OFFICINALIS LEAF OIL (UNII: PTP6R7263M)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73344-101-01	2.5 g in 1 JAR; Type 0: Not a Combination Product	09/29/2019	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/29/2019	

**Labeler** - NINGBO SANTE YING MEDICALAND HEALTHDEVELOPMENT CO.,LTD (404080257)

**Registrant** - NINGBO SANTE YING MEDICALAND HEALTHDEVELOPMENT CO.,LTD (404080257)

## Establishment

Name	Address	ID/FEI	Business Operations
NINGBO SANTE YING MEDICALAND HEALTHDEVELOPMENT CO.,LTD		404080257	manufacture(73344-101)