

ROCKSAUCE ICE- menthol cream

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.

ICY COLD PAIN RELIEF CREAM SOOTHES SORE MUSCLES AND JOINTS

Active ingredients

Menthol 6%

Purpose

Topical Analgesic

Uses:

For temporary relief minor muscular discomfort

Warnings:

For external use only.

Avoid contact with eyes, mucous membrane or broken skin

Keep out of reach of children.

if accidentally ingested, get medical help or contact a Poison Control Center immediately.

Directions:

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

When using this product

do not heat, microwave, and to hot water or any container where heating water may cause splattering and result in burns, use in eyes or directly on mucus membranes, take by mouth or place in nostril, apply to wounds or damaged skin. Do not use otherwise than as directed

Consult a doctor and discontinue use.

if conditions persist for more than 1 week or recur.


Inactive ingredients:

Water, Isopropyl Alcohol, Glycerin, Aloe Barbadensis Leaf Extract, Calendula Officinalis Extract, Arctium Lappa (Burdock) Root Extract, Illex 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


Principal Display Panel

ICY COLD PAIN RELIEF CREAM
SOOTHES SORE MUSCLES & JOINTS



ROCKSAUCE ICE



12 oz (355 ml)



DRUG FACTS	
ACTIVE INGREDIENT	PURPOSE
Menthol 6%	Topical Analgesic
USES: Provides soothing cold to sore muscles and joints.	
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.	
Ask a health professional before use if pregnant or breastfeeding.	
Ask a doctor before using if you have sensitive skin.	
Keep out of reach of children: in case of accidental ingestion, get medical help or call Poison Control Center right away. Not for children 5 years or younger.	
DIRECTIONS: Apply liberally to area of pain and massage until lotion is absorbed into the skin. Repeat 3-4 times daily. 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 Siniensis (Green Tea) Leaf Extract, Melissa Officinalis (Lemon Balm) Leaf Extract, Camphor, Isopropyl Myristate, Carbomer, Triethanolamine, Silicon Dioxide, Tocopheryl (Vitamin E) Acetate	

ROCKTAPE Go through it stronger


RO-SI-12-MED

DESIGNED IN CALIFORNIA
Made in China

ROCKTAPE, INC.
1610 DELL AVE, SUITE 5
CAMPBELL, CA 95008
ROCKTAPE.COM
408.912.ROCK

DO NOT EAT OR DRINK



ROCKSAUCE ICE

menthol cream

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:73344-105

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	6 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER 940 (UNII: 4Q93RCW27E)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GLYCERIN (UNII: PDC6A3C0OX)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73344-105-01	1 in 1 PACKAGE	09/29/2019	
1		355 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	09/29/2019	

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

Establishment

Name	Address	ID/FEI	Business Operations
NINGBO SANTE YING MEDICALAND HEALTHDEVELOPMENT CO.,LTD		404080257	manufacture(73344-105)

Revised: 9/2019

NINGBO SANTE YING MEDICALAND HEALTHDEVELOPMENT CO.,LTD