

ROCKSAUCE FIRE- methyl salicylate, menthol and capsaicin 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.

rocksauce FIRE

Active ingredients

Methyl Salicylate 20%

Menthol USP 10%

Capsaicin 0.002%

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:

2-amino-2-methyl-1-propanol, Aloe barbadensis (aloe vera) Leaf Extract, Arnica Montana Extract, Carbomer, Cetearyl Alcohol, Ethylhexylglycerin, Ethylhexyl, Palmitate, Glycerin,


Methylisothiazolinone, Propylene Glycol, Tocopheryl Acetate, Water


Principal Display Panel

WORKS WITH ROCKTAPE

ROCKSAUCE

FIERY
HOT
PAIN
RELIEF
CREAM





FIRE

SOOTHES SORE
MUSCLES & JOINTS
2.5 g

DRUG FACTS

ACTIVE INGREDIENT	PURPOSE
Methyl Salicylate 20%.....	Topical Analgesic
Menthol 10%.....	Topical Analgesic
Capsaicin 0.002%.....	Topical Analgesic

USES: Provides soothing heat 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: 2-amino-2-methyl-1-propanol, Aloe Barbadosensis (Aloe Vera) Leaf Extract, Arnica Montana Extract, Carbomer, Cetearyl Alcohol, Ethylhexylglycerin, Ethylhexyl, Palmitate, Glycerin, Methylisothiazolinone, Propylene Glycol, Tocopheryl Acetate, Water

ROCKTAPE

DO NOT EAT OR DRINK
NOT FOR RETAIL SALE
DESIGNED IN CALIFORNIA
Made in China

LOT: 2458007
EXP: 09/2019

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

CE
EAC

ROCKSAUCE FIRE

methyl salicylate, menthol and capsaicin cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73344-104
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	0.02 g in 0.1 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.01 g in 0.1 g
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.000002 g in 0.1 g

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: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73344-104-01	1 in 1 PACKAGE	09/29/2019	
1		2.5 g 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(73344-104)

Revised: 9/2019

NINGBO SANTE YING MEDICALAND HEALTHDEVELOPMENT CO.,LTD