ROCKSAUCE FIRE- methyl salicylate, menthol and capsaicin cream NINGBO SANTE YING MEDICALAND HEALTHDEVELOPMENT 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.

FIERY HOT PAIN RELIEF CREAM SOOTHES SORE MUSCLES AND JOINTS

Active ingredients

Methyl Salicylate 20% Menthol USP 10% Capsaicin 0.002%

Purpose

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

Keep out of reach of children.

if accidental ingestion, get medical help or call a Poison Control Center right away.

Directions:

Apply liberally to area of pain and massage untillotion is absorbed into the skin. Repeat 3-4 times daily. Store at 68° to 77°F (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 membrans, take by mouth or place in nostrill, apply to wounds or damaged skin. Do not use otherwise than as directed

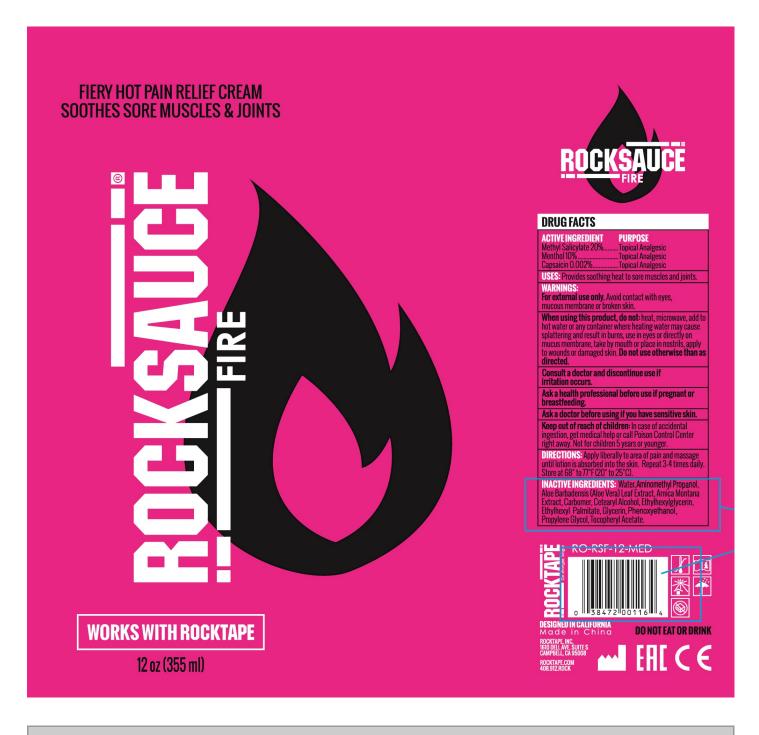
Consult a doctor and discontinus use.

if irritation occurs, ask a health professional before use if pregnant or brastfeeding. before using if you have sensitive skin.

Inactive ingredients:

Water, Aminomethyl Propanol, Aloe Barbadensis (Aloe Vera) Leaf Extract, Arnica Montana Extract, Carbomer, Cetearl Alcohol, Ethylhexylglycerin, Ethylhexyl Palmitate, Glycerin, Phenoxyethanol,

Principal Display Panel



ROCKSAUCE FIRE

methyl salicylate, menthol and capsaicin cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73344-103
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	20 mg in 100 mL	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 mg in 100 mL	
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.2 mg in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
ARNICA MONTANA (UNII: O80TY208ZW)		
ETHYLHEXYL PALMITATE (UNII: 2865993309)		
GLYCERIN (UNII: PDC6A3C0OX)		
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)		
WATER (UNII: 059QF0KO0R)		

I	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73344-103-01	1 in 1 PACKAGE	09/29/2019	
1		88.7 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:73344-103-02	1 in 1 PACKAGE	09/29/2019	
2		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-HEALT-HDEVELOPMENT-CO., LTD-(404080257)

Establishment				
Name	Address	ID/FEI	Business Operations	
NINGBO SANTE YING MEDICALAND HEALTHDEVELOPMENT CO.,LTD		404080257	manufacture(73344-103)	

Revised: 9/2019 NINGBO SANTE YING MEDICALAND HEALTHDEVELOPMENT CO.,LTD