ROCKSAUCE FIERY HOT PAIN RELIEF- methyl salicylate, menthol, capsaicin cream Implus Footcare, 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.

RockSauce®
FIERY HOT PAIN RELIEF GEL
30Z

ACTIVE INGREDIENT

Methyl Salicylate 20%
Menthol 10%
Capsaicin0.002%

PURPOSE

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.

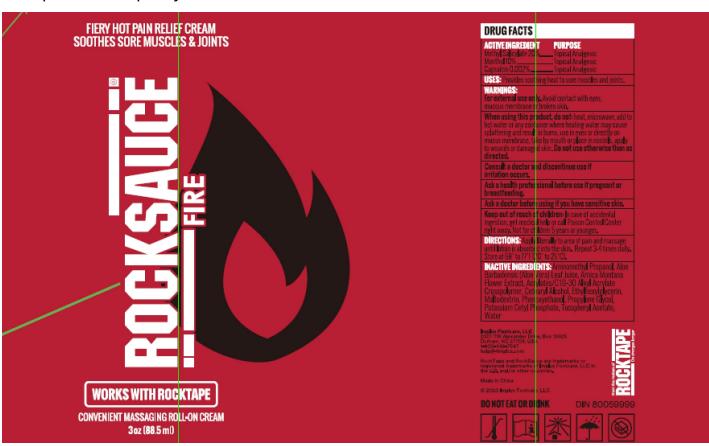
Not for children 5 years or younger.

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:

Aminomethyl Propanol, Aloe Barbadensis (Aloe Vera) Leaf Juice, Arnica Montana Flower Extract, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Cetearyl Alcohol, Ethylhexylglycerin, Maltodextrin, Phenoxyethanol, Propylene Glycol, Potassium Cetyl Phosphate, Tocopheryl Acetate, Water



ROCKSAUCE FIERY HOT PAIN RELIEF methyl salicylate, menthol, capsaicin cream Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:81683-013 Route of Administration TOPICAL Active Ingredient/Active Moiety Ingredient Name Basis of Strength

MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	9.02 g in 88.5 mL
CAPSAICIN (UNII: S07044R1ZM) (CAPSAICIN - UNII:S07044R1ZM)	CAPSAICIN	0.0018 g in 88.5 mL
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:0414PZ4LPZ)	METHYL SALICYLATE	18 g in 88.5 mL

Inactive Ingredients		
Ingredient Name	Strength	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)		
ALOE VERA LEAF (UNII: ZY81Z83H0X)		
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)		
MALTODEXTRIN (UNII: 7CVR7L4A2D)		
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)		
WATER (UNII: 059QF0KO0R)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)		
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)		
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)		
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)		

l	P	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
		NDC:81683- 013-01	88.5 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/18/2021		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	03/18/2021		

Labeler - Implus Footcare, LLC (361531585)

Revised: 3/2021 Implus Footcare, LLC