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 CREAM 2.5g

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.

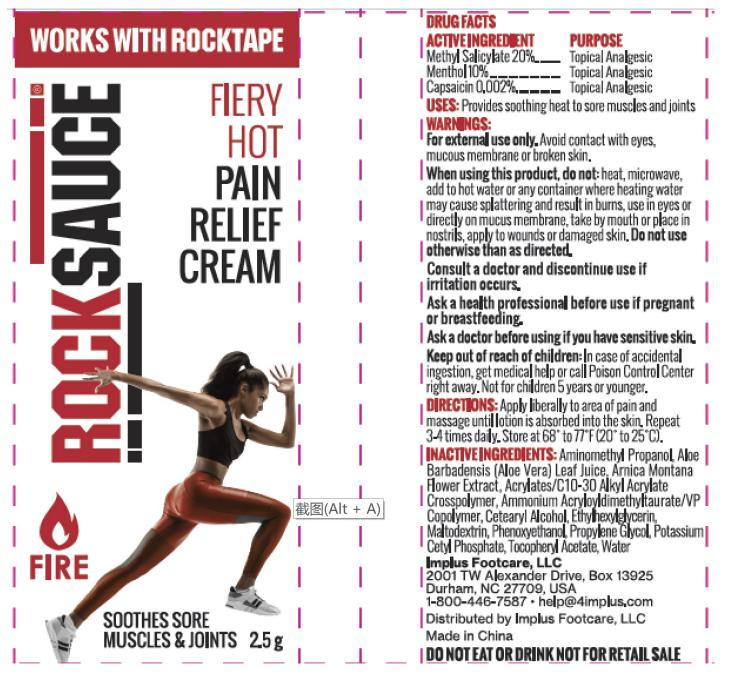
Not for children 5 years or younger.

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, Ammonium Acryloyldimethyltaurate/VP Copolymer, Cetearyl Alcohol, Ethylhexylglycerin, Maltodextrin, Phenoxyethanol, Propylene Glycol, Potassium Cetyl Phosphate, Tocopheryl Acetate, Water



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Product Infor	mation				
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Product Type		HUMAN OTC DRUG	Item Code	e (Source)	NDC:81683-025
Route of Admini	stration	TOPICAL			
Active Ingredi	ent/Active	Moiety			
Ingredient Name				Basis of	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)				Strength MENTHOL	0.25 g in 2.45 mL
					0.00005 g
CAPSAICIN (UNII: S07044R1ZM) (CAPSAICIN - UNII:S07044R1ZM)				CAPSAICIN	in 2.45 mL
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:0414PZ4LPZ)				METHYL SALICYLATE	0.5 g in 2.45 mL
0111.0414124612)					
Inactive Ingre	dients				
		Ingredient Nam	е		Strength
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)					
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)					
ALOE VERA LEAF (UNII: ZY81Z83H0X)					
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)					
MALTODEXTRIN (UNII: 7CVR7L4A2D)					
ETHYLHEXYLGLYC	ERIN (UNII: 147	D247K3P)			
WATER (UNII: 059QF0KO0R)					
PHENOXYETHANOL (UNII: HIE492ZZ3T)					
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)					
POTASSIUM CETY	L PHOSPHATE	(UNII: 03KCY6P7UT)			
ALPHATOCOPHE	ROL ACETATE	(UNII: 9E8X80D2L0)			
CARBOMER INTER	POLYMER TYP	E A (ALLYL SUCROSE CR	OSSLINKED)	(UNII: 59TL3WG5CO)	
AMINOMETHYLPRO	DPANOL (UNII:	LU49E6626Q)			
Packaging					
	D -	des uns Des suintisu	М	arketing Start	Marketing End
# Item Code	Pa	ckage Description		Date	Date
1 NDC:81683-025- 01	2.45 mL in 1 P Product	DUCH; Type 0: Not a Comb	ination 09/2	1/2021	
Marketing	Informat	ion			
Marketing		tion Number or Monog	araph N	Aarketing Start	Marketing End
Category		Citation		Date	Date
OTC monograph not final	part348		09/	/21/2021	

Revised: 9/2021

Implus Footcare, LLC