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 120Z

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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Due durat lufam					
Product Informa	ation				
Product Type		HUMAN OTC DRUG	Item Code	(Source)	NDC:81683-112
Route of Administr	ation	TOPICAL			
	- /				
Active Ingredien	t/Active	Molety			
Ingredient Name				Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)				MENTHOL	36.2 g in 355 mL
CAPSAICIN (UNII: S07044R1ZM) (CAPSAICIN - UNII:S07044R1ZM)			ZM)	CAPSAICIN	0.00724 g in 355 mL
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:0414PZ4LPZ)				METHYL SALICYLATE	72.4 g in 355 mL
Inactive Ingredie	ents				
		Ingredient Nam	е		Strengt
AMMONIUM ACRYLOY	LDIMETHY	LTAURATE/VP COPOLYMI		H9296ZG)	
ARNICA MONTANA FLOWER (UNII: OZ 0E5Y15PZ)					
ALOE VERA LEAF (UNII: ZY81Z83H0X)					
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)					
MALTODEXTRIN (UNII: 7CVR7L4A2D)					
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)					
WATER (UNII: 059QF0K00R)					
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)					
,					
Packaging					
# Item Code	Pa	ckage Description	M	arketing Start Date	Marketing End Date
	5 mL in 1 BC	OTTLE; Type 0: Not a Combi	ination 03/1	8/2021	
110					
	.				
Marketing Information					
Marketing Category	Applicat	tion Number or Monog Citation	graph N	larketing Start Date	Marketing End Date
OTC monograph not final	part348		03/	18/2021	

Labeler - Implus Footcare, LLC (361531585)

Revised: 3/2021