DR SHEFFIELD MUSCLE RUB CREAM- muscle rub cream cream NuCare Pharmaceuticals,Inc.

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.

Drug Facts

Active Ingredients

Menthol - 10% Methyl salicylate - 15%

Purpose

Topical Analgesic Topical Analgesic

Uses

• For temporary relief of minor aches and pains of muscle and joints associated with simple backaches, arthritis, strains, bruises and sprains

Warnings

For external use only

Avoid contact with eyes and mucous membranes

- If conditions worsens, or if symtoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a doctor.
- Do not apply to wounds or damaged skin.
- Do not apply bandage tightly.
- Do not use with a heating pad or on wounds, damaged, broken (open) or irritated skin.
- Discontinue use if excessive irritation of skin develops.
- If pregnant or breast feeding, ask a health professional before use.
- A temporary burning sensation may occur upon application, but generally disappears in a few days.

Keep this and all drugs out of the reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

- Adults and children 2 years of age and older; Apply to affected area not more than 3 to 4 times daily. Children under 2 years of age; consult a doctor.
- Unless treating hands, wash hands throughly wit hsoap and waterimmediately after use.

Other information

- Store at controlled room temperature 20°- 25°C (68° to 77°F)
- Close cap tightly afteruse.

Inactive ingredients

Carbomer, Cetyl Alcohol, Oleth-3 Phosphate, Stearic acid, Triethanolamine, Purified Water

Principal Display Panel -



DR SHEFFIELD MUSCLE RUB CREAM

muscle rub cream cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68071-1624(NDC:11527-057)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	100 mg in 1 g	
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:0414PZ4LPZ)	METHYL SALICYLATE	150 mg in 1 g	

Inactive Ingredients		
Ingredient Name	Strength	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)		
CETYL ALCOHOL (UNII: 936JST6JCN)		
TROLAMINE (UNII: 903K93S3TK)		
WATER (UNII: 059QF0KO0R)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
OLETH-3 PHOSPHATE (UNII: 8Q0Z18J1VL)		
Packaging		

# Item Code	Package Description	Marketing Start Date	Marketing End Date		
1 NDC:68071-1624-5	35 g in 1 BOX; Type 0: Not a Combination Product	08/24/2017			
Marketing Information					
Marketing Info	ormation				
Marketing Info		n Marketing Start Date	Marketing End Date		
0	y Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		

Labeler - NuCare Pharmaceuticals, Inc. (010632300)

Establishment				
Name	Address	ID/FEI	Business Operations	
NuCare Pharmaceuticals,Inc.		010632300	relabel(68071-1624)	

Revised: 2/2021

NuCare Pharmaceuticals, Inc.