

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 symptoms 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 thoroughly with soap and water immediately after use.

Other information

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

Inactive ingredients

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

Principal Display Panel -


NuCare Pharmaceuticals, Inc.

NDC: 68071-2477-5

Muscle Rub
1.25oz Cream
Menthol-10%,
Methyl Salicylate-15%
See manufacturer's label
for full list of ingredients.

Muscle Rub
Lot: 00000 NDC: 68071-2477-05
MFR NDC: 11527-057-40 Exp.: 00-00
Serial# 0000000002

Muscle Rub
Lot: 00000 NDC: 68071-2477-05
MFR NDC: 11527-057-40 Exp.: 00-00
Serial# 0000000002

GTIN 00368071247756
Serial# 0000000002
Exp. Date 00-00
LOT#: 00000

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Distributed by:
Sheffield Pharmaceuticals New
London, CT 06320
Packed by:
NuCare Pharmaceuticals, Inc.
Orange, CA 92867

Rev 01/01/19
WARNING: KEEP OUT OF REACH OF CHILDREN

Product #: R0396125
STORE AT CONTROLLED TEMPERATURE 68-77°F.

Apply every _____ hours
_____ times a day.

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DR SHEFFIELD MUSCLE RUB CREAM

muscle rub cream cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68071-2477(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:O414PZ4LPZ)		METHYL SALICYLATE	150 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CARBOMER 940 (UNII: 4Q93RCW27E)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
TROLAMINE (UNII: 9O3K93S3TK)	
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:68071-2477-5	1 in 1 CARTON	07/15/2021	
1		35 g in 1 TUBE; 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	04/24/2002	

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals,Inc.		010632300	relabel(68071-2477)

Revised: 7/2021

NuCare Pharmaceuticals,Inc.