MUSCLE RUB- menthol, camphor, methyl salicylate cream
Dynarex Corporation

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.

Dynarex Muscle Rub

Active Ingredient

Active Ingredient	**Purpose**
Natural Menthol USP 10%	Topical analgesic
Methyl salicylate 30%	Topical analgesic
Camphor 4%	Topical analgesic

Purpose

Temporary relief of minor aches and pains.

Indications and Usage

Uses

Temporary relief of minor aches and pains of sore muscles and joints associated with simple backache, arthritis, strains, bruises and sprains.

Warnings

For external use only.

- Avoid contact with the eyes or mucous membranes.
- Do not apply to wounds or damaged skin.
- Do not bandage tightly.
- Do not use with heating pad or device.

Stop Use

Stop Use And Ask A Doctor If:

- Condition worsens, or if symptoms persist for more than 7 days,
- symptoms clear up and occur again in a few days
- redness is present or excessive skin irritation develops

If pregnant or breast feeding:

Ask a health professional before use.

Keep Out Of Reach Of Children

KEEP OUT OF REACH OF CHILDREN

If accidentally ingested, get medical help or contact a Poison Control Center immediately.

Dosage & Administration

Directions

- Use only as directed
- Adults and children 12 years of age and older: apply to the affected areas not more than 3 or 4 times daily.
- Children under 12 years of age: Consult a physician.

Other Information

Store at 20° - 25°C (68°-77°F)

Inactive Ingredients

Acrylates/C-10-30 Alkyl acrylate, benzyl alcohol, carbomer, polysorbate 80, trolamine, water.

Principle Display Panel

Dynarex Muscle Rub

dynarex mrub.jpg

MUSCLE RUB

menthol, camphor, methyl salicylate cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67777-406
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
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	40 mg in 1 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	300 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
TROLAMINE (UNII: 9O3K93S3TK)	
(C10-C30)ALKYL METHACRYLATE ESTER (UNII: XH2FQZ38D8)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67777-406-01	85 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/01/2014	

Labeler - Dynarex Corporation (008124539)

Registrant - Dynarex Corporation (008124539)

Establishment

Name	Address	ID/FEI	Business Operations
Blossom Pharmaceuticals		677381470	manufacture(67777-406)

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