

MR DUDLEYS TOPICAL PAIN RELIEF - menthol cream
DUDLEY WELLNESS COMPANY 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 Ingredient:

Menthol 2.5%

Purpose:

Topical Analgesic

Uses:

For the temporary relief of minor arthritis pain, backache, muscle strains and cramps.

Keep out of the reach of children

Warnings:

- For external use only.
- Use only as directed.
- Do not apply to wounds or damaged skin.
- If redness is present, discontinue use and consult a doctor.
- Do not bandage tightly or use a heating pad.
- If the condition persists for more than 5 days, discontinue use and consult a doctor.
- Avoid contact with eyes and other mucous membranes.
- If you are pregnant or nursing a baby, seek the advice of a healthcare professional before using this product.

Directions:

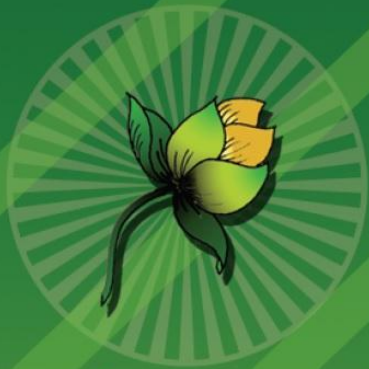
Apply generously and massage into the affected area until thoroughly absorbed into the skin. Repeat as needed for pain, but not more than 4 times per day.

Inactive Ingredients:

Water, SD Alcohol, Glycerine, PEG-40 Hydrogenated Castor Oil, Methyl Salicylate, Caprylic Capric Triglyceride, Sodium Acrylate Copolymer, Eugenol, Methyl Eugenol, Nutmeg Oil, Methyllisoeugenol, Methoxy Eugenol, Blue #1

Product Label

Mr. Dudley's TOPICAL PAIN RELIEF



with nutmeg oil

- Fast Acting
- Deep Penetrating
- Superior Relief

2 oz.

DRUG FACTS

Active Ingredients: Menthol 2.5%Topical Analgesic

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Other Ingredients: Water, SD Alcohol, Glycerine, PEG-40 Hydrogenated Castor Oil, Methyl Salicylate, Caprylic Capric Triglyceride, Sodium Acrylate Copolymer, Eugenol, Methyl Eugenol, Nutmeg Oil, Methyllisoeugenol, Methoxy Eugenol, & Blue #1.

Dst: Dudley Wellness Company Inc.
www.DudleyWellnessCompany.com
Mfg by: Dudley Manufacturing LLC
7210 Cessna Drive
Greensboro, NC 27409
(336) 285-6191



MR DUDLEYS TOPICAL PAIN RELIEF

menthol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58484-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	

ACRYLAMIDE (UNII: 20R035KLCI)	
EUGENOL (UNII: 3T8H1794QW)	
METHYL EUGENOL (UNII: 29T9VA6R7M)	
NUTMEG OIL (UNII: Z1CLM48948)	
METHYL ISOEUGENOL (UNII: 46RN7Q97DE)	
4-ALLYL-2,6-DIMETHOXYPHENOL (UNII: 8VF00YWP89)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58484-100-01	.2 g in 1 BOTTLE		
2	NDC:58484-100-05	1.4 g in 1 BOTTLE		
3	NDC:58484-100-20	57 g in 1 BOTTLE		
4	NDC:58484-100-45	128 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/13/2013	

Labeler - DUDLEY WELLNESS COMPANY INC (078816740)

Establishment

Name	Address	ID/FEI	Business Operations
DUDLEY MANUFACTURING LLC.		830613076	manufacture(58484-100)

Revised: 5/2013

DUDLEY WELLNESS COMPANY INC