# THERACARE MUSCLE AND JOIN PAIN RELIEF CREAM- menthol, methyl salicylate cream Veridian Healthcare

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.

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## TheraCare Muscle & Join Pain Relief Cream

## **Drug Facts**

Menthol 10%

Methyl salicylate 15%

Active ingredients	Purpose
Menthol 10%	Topical analgesic
Methyl salicylate 15%	Topical analgesic

#### Uses

temporarily relieves the minor aches and pains of muscles and joints associated with:

- simple backache
- arthritis
- strains
- bruises
- sprains

## **Warnings**

## For external use only.

#### Do not use

- on wounds or damaged skin
- with a heating pad
- on a child under 12 years of age with arthritis-like conditions

# Ask a doctor before use if you have redness over the affected area

## When using this product

- avoid contact with eyes or mucous membranes
- do not bandage tightly

# Stop use and ask a doctor if

- excessive skin irritation occurs
- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

#### **Directions**

- use only as directed
- adults and children 12 years of age and over: apply to affected area not more than 3 to 4 times daily
- children under 12 years of age: consult a physician.

#### Other information

store at 20° to 25°C (68° to 77°F)

do not use if tube seal under cap is broken

## **Inactive ingredients**

carbomer homopolymer type c, cetostearyl alcohol, cetyl alcohol, glyceryl monostearate, methylparaben, peg-100 stearate, polysorbate 60, propylparaben, stearic acid, trolamine, water.

## TheraCare Muscle & Joint Pain Relief Cream





# THERACARE MUSCLE AND JOIN PAIN RELIEF CREAM

menthol, methyl salicylate cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71101-212
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	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		
CETYL ALCOHOL (UNII: 936JST6JCN)			
PEG-100 STEARATE (UNII: YD01N1999R)			
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)			
CARBOMER 940 (UNII: 4Q93RCW27E)			
METHYLPARABEN (UNII: A2I8C7HI9T)			
TROLAMINE (UNII: 903K93S3TK)			
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)			
PROPYLPARABEN (UNII: Z8IX2SC1OH)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
WATER (UNII: 059QF0KO0R)			
POLYSORBATE 60 (UNII: CAL22UVI4M)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71101-212- 01	1 in 1 CARTON	09/01/2021	
1		56.6 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	09/01/2021	

# Labeler - Veridian Healthcare (830437997)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	

Revised: 8/2022 Veridian Healthcare