

**THERACARE PAIN RELIEVING MUSCLE VANISHING SCENT- menthol,
unspecified form gel
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.

TheraCare Pain Relieving Muscle Vanishing Scent Rub

Drug Facts

Active ingredient

Menthol 2.5%

Purpose

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

- use only as directed
- 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

- 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 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

benzyl alcohol, butylated hydroxytoluene, camphor, carbomer, DMDM hydantoin, edetate disodium, isoceteth-20, isopropyl alcohol, PEG-40 hydrogenated castor oil, sodium hydroxide, water

Questions?

call **866-326-1313** (toll-free)

PRINCIPAL DISPLAY PANEL - 57 g Tube Carton

menthol, unspecified form gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71101-218
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	25 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
ISOCETETH-20 (UNII: O020065R7Z)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71101-218-01	1 in 1 CARTON	11/01/2021	
1		57 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	11/01/2021	

Labeler - Veridian Healthcare (830437997)

Establishment			
Name	Address	ID/FEI	Business Operations
ANICARE PHARMACEUTICALS PRIVATE LIMITED		916837425	manufacture(71101-218)

