MUSCLE RUB PAIN RELIEVER GEL- menthol, unspecified form gel
Universal Distribution Centre LLC

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.

Pain Reliever Gel

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

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

Stop use and ask a doctor if

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

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- adults and children 12 years of age and older: apply to affected area not more than 3 to 4 times daily
- children under 12 years of age: ask a doctor

Other information

store at 20° to 25°C (68° to 77°F)

Inactive ingredients

camphor, carbomer, DMDM hydantoin, isoceteth-20, isopropyl alcohol, PEG-40 hydrogenated castor oil, sodium hydroxide, water

Questions?

call **1-800-223-0182** (toll-free) or **215-273-8755** (collect)

Distributed by:
JOHNSON & JOHNSON
CONSUMER INC.
Skillman, NJ 08558

PRINCIPAL DISPLAY PANEL - 57 g Tube Carton

Extra Strength Muscle Rub

Pain Reliever Gel

Fast Penetrating

MENTHOL 2.5% TOPICAL ANALGESIC GEL

NET WT 1 OZ (35.4 g)

MUSCLE RUB PAIN RELIEVER GEL

menthol, unspecified form gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52000-072

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)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
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:52000-072-02	1 in 1 CARTON	01/24/2021	
1	NDC:52000-072-01	35.4 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	01/24/2021	

Labeler - Universal Distribution Centre LLC (019180459)

Registrant - Anicare Pharmaceutical Pvt. Ltd. (916837425)

Establishment

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(52000-072)

Revised: 2/2022 Universal Distribution Centre LLC