MUSCLE RUB- menthol gel
Universal Distribution Center 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.

U Muscle Rub Gel

Active Ingredient

Menthol 2.5%

Purpose

Topical Analgesic

Uses

- Provides soothing relief of minor arthritis pain, aching muscles, joints and backaches.

Warnings

For external use only. Use only as directed. Keep out of reach of children to avoid accidental poisoning.

- Avoid contact with eyes or mucous membranes.
- Discontinue use if excessive irritation of the skin develops.
- Do not bandage tightly, apply to wounds, broken or irritated skin, or use with a heating pad.
- If condition worsens, or if symptoms persist for more than 10 days or clear-up and occur again within a few days, if skin redness or irritation develops, discontinue use of this product and consult a doctor.
- For arthritis like conditions in children under 12, do not use. Consult a doctor.
- 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 and gently massage until gel disappears.
- Children under 12 years of age: do not use, consult a doctor

Other Information

- Store at controlled room temperature 15°C to 30°C (59°F to 86°F)
- Lot No. & Exp. Date: see crimp of tube.

Inactive Ingredients

Camphor, Carbomer, DMDM Hydantoin, Isoceteth, Isopropyl Alcohol, PEG-40 Hydrogenated Castor Oil, Sodium Hydroxide, Water

PRINCIPAL DISPLAY PANEL

MUSCLE RUB GEL

NET WT 1.25 OZ (35 g)

MUSCLE RUB

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52000-020
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.025 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
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:52000-020-37	1 in 1 BOX	12/13/2020	
1	NDC:52000-020-38	35 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	04/15/2015	

Labeler - Universal Distribution Center LLC (019180459)

Registrant - Anicare Pharmaceuticals Pvt. Ltd (916837425)

Establishment

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(52000-020)

Revised: 2/2022 Universal Distribution Center LLC