**MUSCLE RUB- menthol gel**
**OL PHARMA TECH,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.*

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## ACTIVE INGREDIENT

MENTHOL 2.5%

## PURPOSE

TOPICAL ANALGESIC

## USES

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

- simple backaches
- arthritis
- strains
- bruises
- sprains

## WARNINGS

For external use only

### Do not use

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 your doctor

Stop use and ask your 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**

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

**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**

vitamin E, propylene glycol, polysorbate 80, water, isopropyl alcohol, carbomer interpolymer type A, EDTA , methylparaben, propylparaben

**Questions**

www.drspharmacyusa.com

- original strenghth
- Topical analgesic


23.04.2

# MUSCLE RUB

menthol gel

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:80489-004 |
| **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 |
|---|---|
| **ISOPROPYL ALCOHOL** (UNII: ND2M416302) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **CARBOMER INTERPOLYMER TYPE A (55000 CPS)** (UNII: 59TL3WG5CO) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **EDETATE DISODIUM** (UNII: 7FLD91C86K) | |
| **.ALPHA.-TOCOPHEROL** (UNII: H4N855PNZ1) | |
| **TROLAMINE** (UNII: 9O3K93S3TK) | |
| **POLYSORBATE 80** (UNII: 6OZP39ZG8H) | |
| **METHYLPARABEN** (UNII: A2I8C7HI9T) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | white (TRANSLUCENT) | **Score** | |
| **Shape** | | **Size** | |
| **Flavor** | | **Imprint Code** | |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:80489-004-01 | 1 in 1 CARTON | 01/01/2021 | |
| **1** | | 28.3 g in 1 TUBE; Type 0: Not a Combination Product | | |
| **2** | NDC:80489-004-02 | 1 in 1 CARTON | 01/01/2021 | |
| **2** | | 49.6 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 | 01/01/2021 | |

## Labeler - OL PHARMA TECH,LLC (021170377)

## Registrant - OL PHARMA TECH,LLC (021170377)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| OL PHARMA TECH,LLC (Drs. pharmacy) | | 021170377 | manufacture(80489-004) |

Revised: 10/2023

OL PHARMA TECH,LLC