

VANISHING SCENT MUSCLE RUB GEL- menthol gel
McCure Health Solutions Inc.

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.

Vanishing Scent Muscle Rub 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 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 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 between 20 C and 25 C (68 F and 77 F) • Lot No. & Exp. Date. see box or crimp of tube

Inactive ingredients

CARBOMER 940, DL-CAMPHOR, ISOPROPANOL, METHYLPARABEN, POLYSORBATE 60, POTASSIUM SORBATE, PURIFIED WATER, STEARYL ALCOHOL, TROLAMINE

Product Label



VANISHING SCENT MUSCLE RUB GEL

menthol gel

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:52486-012 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|--------------|
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 25 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| CARBOMER 940 (UNII: 4Q93RCW27E) | |
| CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) | |
| ISOPROPYL ALCOHOL (UNII: ND2M416302) | |
| METHYL PARABEN (UNII: A218C7H9T) | |
| POLYSORBATE 60 (UNII: CAL22UVI4M) | |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | |
| WATER (UNII: 059QF0KO0R) | |
| STEARYL ALCOHOL (UNII: 2KR89I4HIY) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:52486-012-57 | 1 in 1 CARTON | 03/27/2015 | |
| 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 | 03/27/2015 | |

Labeler - McCure Health Solutions Inc. (053034873)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------------------------|---------|-----------|------------------------|
| Jiangsu Dedi Medical Device Co., Ltd. | | 544458936 | manufacture(52486-012) |