

**MUSCLE RUB- pain relieve cream**  
**AFN BROKER 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.*

**DRUG FACTS**

**ACTIVE INGREDIENTS**

Active Ingredients	Purpose
Camphor 4%.....	Topical analgesic
Menthol 10%.....	Topical analgesic
Methyl Salicylate 30%.....	Topical analgesic

**ASK A DOCTOR BEFORE USE**

**Ask a doctor before use if you have redness over the affected area.**

**Directions • use only as directed**

- 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

**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

**INACTIVE INGREDIENTS**

**Inactive Ingredients** Carbomer 940, edetate disodium, glyceryl stearate se, lanolin, polysorbate 80, potassium hydroxide, purified water, stearic acid, trolamine

**KEEP OUT OF REACH OF CHILDREN TO AVOID ACCIDENTAL INGESTION**

**Keep out of reach of children to avoid accidental ingestion.**

If swallowed, get medical help or contact a Poison Control Center immediately.

## STOP USE AND ASK A DOCTOR IF

### 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

## USES

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

- Simple backache • arthritis • strains • bruises • sprains

## WARNINGS

### Warnings

For external use only

## WHEN USING THIS PRODUCT

### When using this product

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

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## STORAGE

**Other information** • store at 20° to 25°C (68° to 77°F) Do not use if tube seal under cap is broken, missing or if the tube tip is cut prior to opening

## PURPOSE

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## DIRECTIONS

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**MUSCLE RUB**

pain relieve cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72004-002
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>METHYL SALICYLATE</b> (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	0.3 g in 100 g
<b>CAMPHOR (SYNTHETIC)</b> (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	0.04 g in 100 g
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.1 g in 100 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>GLYCOL STEARATE SE</b> (UNII: 6YLY96TQL6)	0.025 g in 100 g
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	0.02 g in 100 g
<b>ACETYLATED LANOLIN</b> (UNII: 2X654GD19H)	0.05 g in 100 g
<b>POTASSIUM HYDROXIDE</b> (UNII: WZH3C48M4T)	0.008 g in 100 g
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	0.1 g in 100 g
<b>WATER</b> (UNII: 059QF0KO0R)	0.264 g in 100 g
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	0.08 g in 100 g
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	0.75 g in 100 g

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72004-002-35	35 g in 1 JAR; Type 0: Not a Combination Product	08/01/2018	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	08/01/2018	

**Labeler** - AFN BROKER LLC (030117252)

