ULTRA STRENGTH PAIN RELIEF BALM- camphor, 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.

Ultra Strength Pain Relief Balm

Drug Facts

Active ingredients

Camphor 11%

Menthol 11%

Purpose

Topical analgesic

Uses

For temporary relief minors aches and pains of muscles and joints associated with over-exertion, simple backache, arthritis, strains and sprains.

Warnings

For external use only

When using this product

- Avoid contact with eyes and mocous membranes
- Do not apply to open wounds or damaged skin
- Do not bandage or use heating pad

Stop use and ask a doctor if

- Condition worsens
- Severe skin irritation occurs.
- Pain persists for more than seven days
- Pain clears up and then recurs a few days later

If pregnant or breast-feeding,

ask a healthcare professional before use

Keep out of reach of children.

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

Directions

• Rub well on the affected area. Repeat 3 to 4 times daily

Other information

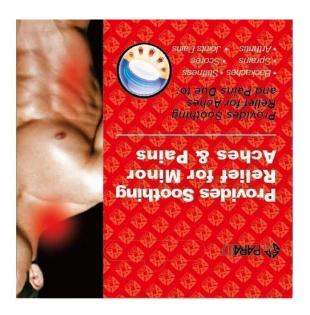
This product may cause allergic reaction in some individuals. Test on small area before use.

Inactive ingredients

CAJUPUT OIL, CLOVE OIL, DEMENTHOLIZED MINT OIL, PARAFFIN PETROLATUMA

Product Label





ULTRA STRENGTH PAIN RELIEF BALM

camphor, menthol gel

| Product Information | | | | |
|-------------------------|----------------|--------------------|---------------|--|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:52486-013 | |
| Route of Administration | TOPICAL | | | |

| Active Ingredient/Active Moiety | | | | |
|--|-------------------|---------------|--|--|
| Ingredient Name | Basis of Strength | Strength | | |
| CAMPHOR (NATURAL) (UNII: N20 HL7Q941) (CAMPHOR (NATURAL) - UNII:N20 HL7Q941) | CAMPHOR (NATURAL) | 110 mg in 1 g | | |
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 110 mg in 1 g | | |

| Inactive Ingredients | | | |
|---------------------------------|----------|--|--|
| Ingredient Name | Strength | | |
| CAJUPUT O IL (UNII: J3TO6BUQ37) | | | |
| CLOVE OIL (UNII: 578389 D6 D0) | | | |

| Ш | Packaging | | | | |
|---|------------------|---|-----------------------------|---------------------------|--|
| Ш | # Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| | NDC:52486-013-18 | 1 in 1 CARTON | 03/27/2015 | | |
| | 1 | 18 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(52486-013) | |

Revised: 12/2016 McCure Health Solutions Inc.