MEDISTIK COOLING ROLL-ON- menthol, camphor solution
Medistik 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.

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MEDISTIK COOLING ROLL-ON

ACTIVE INGREDIENTS
Menthol 10%
Camphor 4%

PURPOSE
Topical Analgesic

USES
For the temporary relief of sore muscles and joints associated with
• simple backache
• arthritis
• strains
• sprains
• bruises
• cramps

WARNINGS
When using this product
• use only as directed
• avoid getting into the eyes and mucous membranes
• do not bandage tightly or use with a heating pad
• do not apply to wounds or damaged skin

Stop use and ask doctor if
• condition worsens
• symptoms persist for more than 7 days or clear up and occur again within a few days
• excessive skin irritation or redness occurs

If pregnant or breast-feeding, ask a health professional before use.

DIRECTIONS
• For use on adults and children over 12 years of age and older: Apply product on affected area, not more than 4 times daily
• children under 12 years of age: ask a doctor

INACTIVE INGREDIENTS
Denatured alcohol, Water, Peppermint oil, Glycerin, Polyacrylate Crosspolymer-6, MSM, Ilex
paraguariensis leaf extract, Glucosamine sulphate, Chondroitin sulphate, Folic acid, Vitamin C, Vitamin D.

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

**MEDISTIK COOLING ROLL-ON**
menthol, camphor solution

**Product Information**

- **Product Type**: HUMAN OTC DRUG
- **Route of Administration**: TOPICAL
- **Item Code (Source)**: NDC:77108-103

**Active Ingredient/Active Moiety**

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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</thead>
<tbody>
<tr>
<td>MENTHOL (UNII: L7T10EIP3A)</td>
<td>MENTHOL</td>
<td>10 g in 100 mL</td>
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<tr>
<td>CAMPHOR OIL (UNII: 75IZZ8Y727)</td>
<td>CAMPHOR OIL</td>
<td>4 g in 100 mL</td>
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**Inactive Ingredients**

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALCOHOL (UNII: 3K9958V90M)</td>
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<tr>
<td>WATER (UNII: 059QF0KO0R)</td>
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</tr>
<tr>
<td>PEPPERMINT OIL (UNII: AV092KU41H)</td>
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</table>
GLYCERIN (UNII: PDC6A3C0OX)
AMMONIUM ACRYLOYLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOPROPANE TRIACRYLATE CROSSTLINKED (45000 MPA.S) (UNII: Q7UJ015FF9)
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)
CHONDROITIN SULFATE (CHICKEN) (UNII: 7VZ9466BAB)
FOLIC ACID (UNII: 935E97BOY8)
ASCORBIC ACID (UNII: PQ6CK8PD0R)
VITAMIN D (UNII: 9VU1K44GP)

Packaging

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<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<td>89 mL in 1 BOTTLE; Type 0: Not a Combination Product</td>
<td>05/14/2020</td>
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Marketing Information

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<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<td>OTC monograph not final</td>
<td>part348</td>
<td>05/14/2020</td>
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Labeler - Medistik Inc (204132562)

Revised: 5/2020