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
Menthol 15%

Purpose
External analgesic

Uses
For the temporary relief of minor aches and pains of muscles and joints due to:
simple backache
arthritis
strains
bruises
sprains

Warnings
For external use only

Do not use
on wounds
on damaged skin
if excessive irritation develops

When using this product
avoid contact with the eyes
do not bandage tightly

Stop use and ask a doctor if
condition worsens
symptoms persist for more than 7 days
symptoms clear up and occur again within a few days
when using for pain of arthritis if:
pain persists for more than 10 days
redness is present
in conditions affecting children under 12 years of age

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

Directions
Adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily. Children under 2 years of age: Do not use, consult your doctor.

Other information
keep container tightly closed
store at 15∫ to 30C (59 to 86F)

Inactive ingredients
Baikal Skullcap (Huang-Qin) Root, Chinese Licorice (Gan-Zao) Root, Cinnamon Oil, Dragon’s Blood (Xue-Jie) Resin, Peppermint Oil, and Tea Oil.

Questions or comments? (888)221-3496 M-F 9am to 5pm
you may also report serious side effects to this phone number

PO SUM ON MEDICATED OIL, EXTERNAL ANALGESIC, NDC 54155-052-01 Net wt. 1 fl. oz (30ml.)
PO SUM ON MEDICATED OIL EXTERNAL ANALGESIC

Drug Facts
Active Ingredients: Menthol 15%... External use only

Uses:
For the temporary relief of minor aches and pains of muscles and joints due to:
- Simple backache
- Arthritis
- Strains
- Bruises
- Sprains

Warnings:
For external use only
Do not use:
- On wounded
- On damaged skin
- If excessive irritation develops

When using this product:
- Avoid contact with the eyes
- Do not bandage tightly

Stop use and ask a doctor if:
- Condition worsens
- Symptoms persist for more than 7 days
- Symptoms clear up and occur again within a few days
- When using for pain of arthritis if:
- Pain persists for more than 10 days

Drug Facts (continued)
- Redness is present
- In conditions affecting children under 12 years of age

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

Directions:
- Adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily.
- Children under 2 years of age: Do not use. Consult a doctor.

Inactive ingredients:
- Baikal Skullcap (Huang-Qin) Root, Chinese Licorice (Gan-Zao) Root, Chinnamon Oil, Dragon's Blood (Xue-Jie) Resin, Peppermint Oil, and Tea Oil.

Questions or Comments?
(888) 221-3496
M-F, 9 am to 5 pm
- You may also report serious side effects to this phone number.
**Product Type**  | HUMAN OTC DRUG  | **Item Code (Source)**  | NDC:54155-052
---|---|---|---
**Route of Administration**  | TOPICAL

### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)</td>
<td>MENTHOL</td>
<td>15 g in 100 mL</td>
</tr>
</tbody>
</table>

### Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCUTELLARIA BAICALENSIS ROOT (UNII: 7J95K7ID2S)</td>
<td></td>
</tr>
<tr>
<td>GLYCyrRHiza URALENSIS WHOLe (UNII: 8XW1DS8UIR)</td>
<td></td>
</tr>
<tr>
<td>CINNAMON OIL (UNII: E5GY4I6YCZ)</td>
<td></td>
</tr>
<tr>
<td>DAEMONOROPS DRACO RESIN (UNII: 787Z7N9UCU)</td>
<td></td>
</tr>
<tr>
<td>PEPPERMINT OIL (UNII: AV092KU4JH)</td>
<td></td>
</tr>
<tr>
<td>CAMELLIA OIL (UNII: T1PE06G0VE)</td>
<td></td>
</tr>
</tbody>
</table>

### Product Characteristics

| Color | brown |
| Shape | |
| Flavor | |
| Contains | |

### Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:54155-052-01</td>
<td>1 in 1 CAN</td>
<td>05/10/2004</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>NDC:54155-052-02</td>
<td>1 in 1 BOX</td>
<td>05/10/2004</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>5.6 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>OTC monograph not final</td>
<td>part348</td>
<td>05/10/2004</td>
<td></td>
</tr>
</tbody>
</table>

**Labeler**  | PO SUM ON MEDICINE FACTORY LIMITED (664986375)

**Establishment**

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
</tr>
</thead>
</table>