

**MOMR RUMAIAIAN HERBAL BANDAGE- l-menthol, methyl salicylate patch**  
**MARYHELEN ORIENTAL MEDICINE RESEARCH**

*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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**MOMR Rumaian Herbal Bandage**

**Active ingredients: (each patch contains 3 grams)**

L-MENTHOL – 3.0%  
Methyl Salicylate – 10%

**PURPOSE**

**EXTERNAL ANALGESIC**

**Keep out reach of children to avoid accidental poisoning. If swallowed, get medical help or consult a poison control center right away.**

*USES* for the relief of pain in breasts.

**WARNINGS – For external use only.**

**Do not use:**

- On wounds
- On infected or damaged skin
- While exercising or performing sweaty activities (yoga, swimming, and etc.,)

**When using this product:**

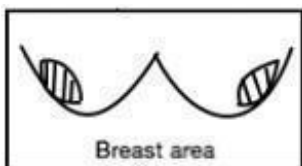
- Avoid contact with eyes or mouth
- Do not bandage tightly

**Stop use and ask a doctor if:**

- Condition worsens
- Symptom clear up and occur again within a few days.
- Symptom persist for more than 7 days.
- Nausea, vomiting, abdominal discomfort, diarrhea, or skin rash occurs.
- Excessive irritation of the skin develops

**Direction:**

- For adult women use only
- Take Rumaian patches out of the box and place on the side of each of the breasts.




- Use once a day, leave both patches on for 3-6 hours
- Remove patches after usage and place back in the box
- Patches are effective for 30 days

**Other information:**


- When storing, keep patches away from sun exposure

**Inactive ingredients:** Cotton, Oldenlandia Diffusa, Angelica sinensis and Rehmannia glutinosa.

**Packaging**



Maryhelen Oriental Medicine Research, LLC

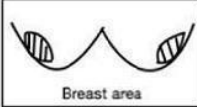


*Rumaian*  
Herbal Bandage  
External Analgesic

Net Weight: 0.2 oz. (6 grams)  
Contains two patches  
3.5" x 3.0" (8.9 x 7.6 cm)

**Made in USA** For external use only

**External Pain Relieving Bandage**

| DRUG FACTS  |  |
|---|--|
| <b>Active ingredients: (each patch contains 3 grams)</b>  | <b>PURPOSE</b>                           |
| L-MENTHOL - 3.0%<br>Methyl Salicylate - 10%   | EXTERNAL ANALGESIC<br>EXTERNAL ANALGESIC |
| <b>USES</b> for the relief of pain in breasts   |  |
| <b>WARNINGS</b> -For external use only.   |  |
| <b>Do not use:</b>  |  |
| <ul style="list-style-type: none"> <li>■ On wounds</li> <li>■ On infected or damaged skin</li> <li>■ While exercising or performing sweaty activities (yoga, swimming, and etc)</li> </ul>  |  |
| <b>When using this product:</b>   |  |
| <ul style="list-style-type: none"> <li>■ Avoid contact with eyes or mouth</li> <li>■ Do not bandage tightly</li> </ul>  |  |
| <b>Stop use and ask a doctor if:</b>  |  |
| <ul style="list-style-type: none"> <li>■ Condition worsens</li> <li>■ Symptom clear up and occur again within a few days.</li> <li>■ Symptom persist for more than 7 days.</li> <li>■ Nausea, vomiting, abdominal discomfort, diarrhea, or skin rash occurs</li> <li>■ Excessive irritation of the skin develops</li> </ul> |  |
| <b>Inactive ingredients:</b> Cotton, Oldenlandia Diffusa, Angelica sinensis and Rehmannia glutinosa   |  |
| Keep out reach of children to avoid accidental poisoning. If swallowed, get medical help or consult a poison control center right away.   |  |
| <b>Direction:</b>   |  |
| <ul style="list-style-type: none"> <li>■ For adult women use only</li> <li>■ Take Rumaian patches out of the box and place on the side of each of the breasts</li> </ul>  |  |
|  <p>Breast area</p>  |  |
| <ul style="list-style-type: none"> <li>■ Use once a day, leave both patches on for 3-6 hours</li> <li>■ Remove patches after usage and place back in the box</li> <li>■ Patches are effective for 30 days</li> </ul>  |  |
| <b>Other information:</b>   |  |
| <ul style="list-style-type: none"> <li>■ When storing, keep patches away from sun exposure</li> </ul>   |  |

U.S. Distributor:  
Maryhelen Oriental  
Medicine Research LLC  
Corte Madera, CA 94925

**MOMR RUMAIAN HERBAL BANDAGE**

l-menthol, methyl salicylate patch

**Product Information**

|                                |                |                           |                |
|--------------------------------|----------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:69559-3921 |
| <b>Route of Administration</b> | TOPICAL        |                           |                |

**Active Ingredient/Active Moiety**

| Ingredient Name   | Basis of Strength | Strength |
|---|-------------------|----------|
| LEVOMENTHOL (UNII: BZ1R15MTK7) (LEVOMENTHOL - UNII:BZ1R15MTK7)          | LEVOMENTHOL       | 0.09 g   |
| METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ) | METHYL SALICYLATE | 0.3 g    |

**Inactive Ingredients**

| Ingredient Name                        | Strength |
|--|----------|
| COTTON FIBER (UNII: 70LDW53ROO)        |          |
| OLDENLANDIA DIFFUSA (UNII: 291PPU5K9I) |          |

ANGELICA SINENSIS WHOLE (UNII: 697D19QDBN)

REHMANNIA GLUTINOSA WHOLE (UNII: 37S3F886KQ)

### Packaging

| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:69559-3921-3 | 2 in 1 BAG          |                      |                    |

### Marketing Information

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part348                                  | 12/23/2014           |                    |

**Labeler** - MARYHELEN ORIENTAL MEDICINE RESEARCH (079650440)

### Establishment

| Name                                 | Address | ID/FEI    | Business Operations     |
|--------------------------------------|---------|-----------|-------------------------|
| MARYHELEN ORIENTAL MEDICINE RESEARCH |         | 079650440 | manufacture(69559-3921) |

Revised: 2/2015

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