

## **MEDICATED PAIN RELIEF PATCH- camphor, menthol, methyl salicylate patch Kroger Company**

*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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### **Medicated Pain Relief Patch**

#### **Active Ingredients**

Active Ingredients Purpose

Camphor 3.1% .....Topical Analgesic

Menthol 6.0% .....Topical Analgesic

Methyl Salicylate 10.0% .....Topical Analgesic

#### **For External Use Only**

**Allergy alert:** If prone to allergic reaction from aspirin or salicylates, consult a doctor before use

#### **Do not use:**

- On wounds or damaged skin
- With a heating pad
- If you are allergic to any ingredients of this product

#### **When using this product**

- Use only as directed
- Avoid contact with eyes, mucous membranes or rashes
- Do not bandage tightly
- Do not use at the same time as other topical analgesics
- Dispose of used patch in manner that keeps product away from childrens and pets. Used patches still contain the drug product that can produce serious adverse effects if a child or pet chews or ingests this patch.

#### **Stop use and consult a doctor**

- If rash, itching or excessive skin irritation develops
- If condition worsens
- if symptoms last more than 7 days or clear up and occur again with a few days

#### **Keep out of reach of children**

If swallowed, get medical help or contact a Poison Control Center right away

## **Uses**

For temporary relief of minor aches and pains of muscles and joints associated with arthritis, simple backache, strains, sprains, and bruises.

## **Directions**

**Adults and children 12 years of age and over:** Clean and dry affected area. Remove patch from film, apply to affected area not more than 3 to 4 times daily. Remove patch from the skin after at most, 8-hour application.

**Children under 12 years of age:** consult physician.

## **Inactive Ingredients**

Hydrogenated Poly, Pentaerythrityl Tetra-di-t-butyl Hydroxyhydrocinnamate, Petroleum, Styrene / Isoprene Copolymer

## **Indication and Usage**

For temporary relief of minor aches and pains.

DIST. BY  
The Kroger Co.  
Cincinnati, OH 45202

Made in China

## **Medicated Pain Relief Patch Label**



**Other Information:** Store in clean, dry place outside of direct sunlight. Protect from excessive moisture.

| <b>MEDICATED PAIN RELIEF PATCH</b>        |                        |                           |                 |
|---|------------------------|---------------------------|-----------------|
| camphor, menthol, methyl salicylate patch |                        |                           |                 |
| <b>Product Information</b>                |                        |                           |                 |
| <b>Product Type</b>                       | HUMAN OTC DRUG         | <b>Item Code (Source)</b> | NDC:30142-892   |
| <b>Route of Administration</b>            | TOPICAL                |                           |                 |
| <b>Active Ingredient/Active Moiety</b>    |                        |                           |                 |
|   | <b>Ingredient Name</b> | <b>Basis of Strength</b>  | <b>Strength</b> |

|   |                     |                   |
|---|---------------------|-------------------|
| <b>CAMPHOR (SYNTHETIC)</b> (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET) | CAMPHOR (SYNTHETIC) | 3.1 g<br>in 100 g |
| <b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)                         | MENTHOL             | 6 g in 100 g      |
| <b>METHYL SALICYLATE</b> (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)        | METHYL SALICYLATE   | 10 g<br>in 100 g  |

### Inactive Ingredients

| Ingredient Name   | Strength |
|---|----------|
| <b>HYDROGENATED POLYDECENE (550 MW)</b> (UNII: U333RI6EB7)  |          |
| <b>PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE)</b> (UNII: 255PIF62MS) |          |
| <b>LIQUID PETROLEUM</b> (UNII: 6ZAE7X688J)  |          |
| <b>STYRENE/ACRYLAMIDE COPOLYMER (MW 500000)</b> (UNII: 5Z4DPO246A)                                  |          |

### Product Characteristics

|                 |        |                     |  |
|-----------------|--------|---------------------|--|
| <b>Color</b>    |        | <b>Score</b>        |  |
| <b>Shape</b>    | SQUARE | <b>Size</b>         |  |
| <b>Flavor</b>   |        | <b>Imprint Code</b> |  |
| <b>Contains</b> |        |                     |  |

### Packaging

| # | Item Code        | Package Description                               | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:30142-892-60 | 60 in 1 BOX                                       | 11/15/2017           |                    |
| 1 |                  | 9 g in 1 PATCH; 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                                  | 10/12/2017           |                    |

**Labeler** - Kroger Company (006999528)

### Establishment

| Name                             | Address | ID/FEI    | Business Operations    |
|----------------------------------|---------|-----------|------------------------|
| Foshan Aqua Gel Biotech Co.,Ltd. |         | 529128763 | manufacture(30142-892) |