

PAIN RELIEF PATCHES- camphor, menthol, methyl salicylate patch

Veridian Healthcare

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.

Pain Relief Patches

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.

Pain Relief Patch Label



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

PAIN RELIEF PATCHES

camphor, menthol, methyl salicylate patch

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:7110 1-907 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|---------------------|----------------|
| CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET) | CAMPHOR (SYNTHETIC) | 3.1 g in 100 g |
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 6 g in 100 g |
| METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ) | METHYL SALICYLATE | 10 g in 100 g |

Inactive Ingredients

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

Product Characteristics

| | | | |
|----------|--------|--------------|--|
| Color | | Score | |
| Shape | SQUARE | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:71101-907-20 | 20 in 1 BOX | 06/01/2017 | |
| 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 | 06/01/2017 | |

Labeler - Veridian Healthcare (830437997)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|----------------------------------|---------|-----------|------------------------|
| Foshan Aqua Gel Biotech Co.,Ltd. | | 529128763 | manufacture(71101-907) |