**THERA CARE HOT AND COLD MEDICATED PATCH- menthol 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.*

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**Thera Care Hot and Cold Medicated Patch**

## ACTIVE INGREDIENT

Active Ingredient .....Purpose
Menthol 5%.....Topical Analgesic

## INACTIVE INGREDIENT

CMC, Dihydroxy aluminum Aminoacetate, Glycerin, Kaolin, Mineral Oil, Methylparaben, Petrolatum, Polyacrylic Acid, Polysorbate 80, Propylene Glycol, Propylparaben, PVP, Sodium Polyacrylate, Tartaric Acid, Titanium Dioxide, Water

## KEEP OUT OF REACH OF CHILDREN

If swallowed, get medical help or contact a Poison Control

## INDICATIONS & USAGE

Temporarily relieves minor pain associated with: ■ arthritis ■ simple backache ■ bursitis ■ tendonitis ■ muscle strains ■ muscle sprains ■ bruises ■ cramps

## WARNINGS

**For External Use Only.**

## DOSAGE & ADMINISTRATION

Adults and children over 12 years: Carefully remove backing from patch. Apply sticky side of patch to affected area.

Wear one patch up to 8 hours. Repeat as necessary, but no more than 4 times daily. Reseal pouch after opening.

Children 12 years or younger: Consult a physician.

## PURPOSE

Topical Analgesic

### When using this product

Use only as directed ■ Don’t bandage tightly or use with heating pad
■ Avoid contact with eyes and mucous membranes ■ Don’t apply to wounds or damaged skin.

### Stop use and ask a doctor

If condition worsens ■ If redness is present ■ If irritation develops
■ If symptoms persist for more than 7 days or clear up and occur again within a few days.

**If pregnant or breastfeeding**

ask a health professional before use.


# THERA CARE HOT AND COLD MEDICATED PATCH

menthol patch

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:71101-953 |
| **Route of Administration** | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **MENTHOL** (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 5 g in 100 g |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **CARBOXYMETHYLCELLULOSE** (UNII: 05JZI7B19X) | |
| **MINERAL OIL** (UNII: T5L8T28FGP) | |
| **PETROLATUM** (UNII: 4T6H12BN9U) | |
| **DIHYDROXYALUMINUM AMINOACETATE** (UNII: DO250MG0W6) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **KAOLIN** (UNII: 24H4NWX5CO) | |
| **METHYLPARABEN** (UNII: A2I8C7HI9T) | |
| **SODIUM POLYACRYLATE (2500000 MW)** (UNII: 05I15JNI2J) | |
| **POLYACRYLIC ACID (250000 MW)** (UNII: 9G2MAD7J6W) | |
| **POLYSORBATE 80** (UNII: 6OZP39ZG8H) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **PROPYLPARABEN** (UNII: Z8IX2SC1OH) | |
| **POVIDONE, UNSPECIFIED** (UNII: FZ989GH94E) | |
| **TARTARIC ACID** (UNII: W4888I119H) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **WATER** (UNII: 059QF0KO0R) | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:71101-953-05 | 5 in 1 BOX | 05/01/2018 | |
| **1** | | 9 g in 1 POUCH; 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 | 05/01/2018 | |

## Labeler - Veridian Healthcare (830437997)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Foshan Aqua Gel Biotech Co.,Ltd. | | 529128763 | manufacture(71101-953) |

Revised: 7/2020

Veridian Healthcare