

**THERA CARE COLD HOT 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 Cold Hot Medicated Patch**

**ACTIVE INGREDIENT**

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

**PURPOSE**

Topical Analgesic

**INDICATIONS & USAGE**

Temporarily relieves minor aches and pains of muscles and joints: ■ arthritis ■ simple backache ■ bursitis ■ tendonitis

■ muscle strains ■ muscle sprains ■ bruises ■ cramps

**WARNINGS**

**For External Use Only.**

**When using this product**

Use only as directed

- Rare cases of serious burns have been reported with products of this type
- Don't bandage tightly or use with a heating pad
- Avoid contact with eyes and mucous membranes ■ Don't apply to wounds or damaged skin. ■ Do not use at the same time as other topical analgesics.

**Stop use and ask a doctor**

If condition worsens ■ redness is present ■ If irritation develops ■ symptoms persist for more than 7 days or clear up and occur again within a few days. ■ You experience signs of skin injury, such as pain, swelling, or blistering where the product was applied.

**If pregnant or breastfeeding**

ask a health professional before use.

**KEEP OUT OF REACH OF CHILDREN**

Do not use in infants. If swallowed, get medical help or contact a Poison Control Center (800-222-1222) right away

**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 3 times daily. Discard patch after single use. Reseal pouch after opening. Children under 12 years of age: Consult a physician.

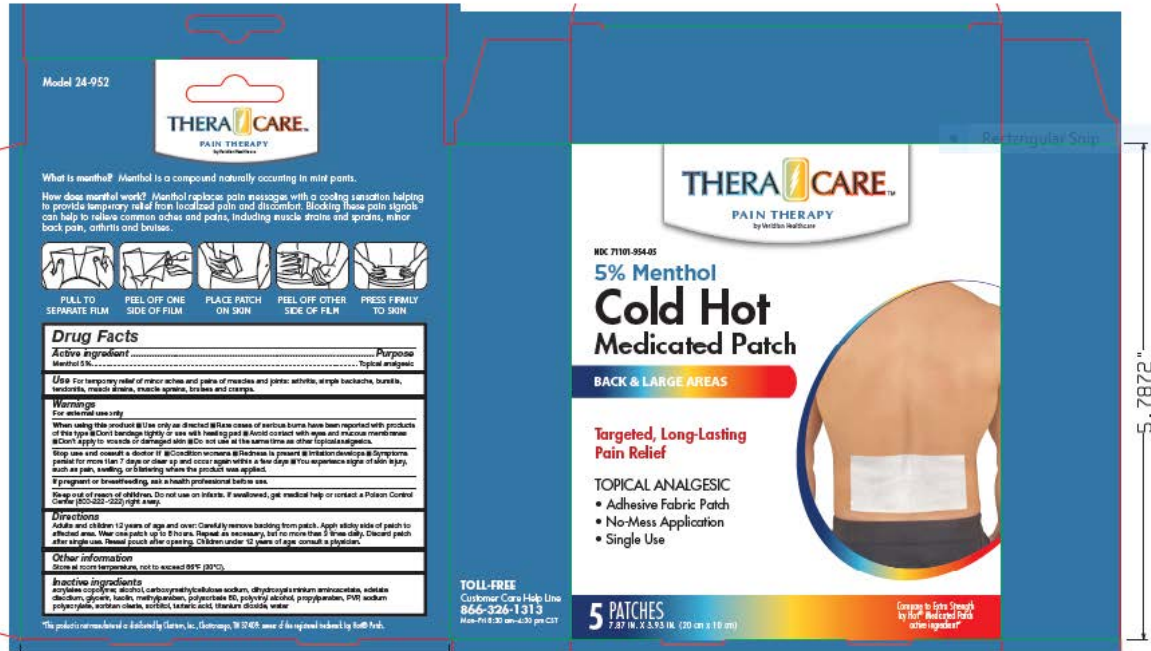
**Other Information**

Store at room temperature, not to exceed 86F (30C)

**INACTIVE INGREDIENT**

Acrylates Copolymer, Alcohol, Carboxymethylcellulose sodium, Edetate Disodium, Dihydroxyaluminium amino acetate, Glycerin, Kaolin, Methylparaben, Polysorbate 80, Polyvinyl alcohol, Propylparaben, PVP, Sodium Polyacrylate, Sorbitan oleate, Sorbitol, Tartaric Acid, Titanium Dioxide Water





# TheraCare Cold Hot Medicated Patch

menthol patch

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71101-954
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
<b>CARBOXYMETHYLCELLULOSE</b> (UNII: 05JZ17B19X)	
<b>DIHYDROXYALUMINUM AMINOACETATE</b> (UNII: DO250MG0W6)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>KAOLIN</b> (UNII: 24H4NWX5CO)	

<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)
<b>SODIUM POLYACRYLATE (250000 MW)</b> (UNII: 05I15JNI2J)
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)
<b>TARTARIC ACID</b> (UNII: W4888I119H)
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)
<b>WATER</b> (UNII: 059QF0KO0R)
<b>POLYVINYL ALCOHOL (100000 MW)</b> (UNII: 949E52Z6MY)
<b>ALCOHOL</b> (UNII: 3K9958V90M)
<b>ACRYLIC ACID/DIMETHICONE METHACRYLATE/ETHYLHEXYL ACRYLATE COPOLYMER</b> (UNII: E5024Y9FFQ)
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)
<b>SORBITOL</b> (UNII: 506T60A25R)
<b>PEG-6 SORBITAN OLEATE</b> (UNII: 58O7V09UCI)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71101-954-05	5 in 1 BOX	10/01/2020	
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	10/01/2020	

**Labeler** - Veridian Healthcare (830437997)

### Establishment

Name	Address	ID/FEI	Business Operations
Unexo Life Sciences, Private Limited		872260479	manufacture(71101-954)

Revised: 1/2023

Veridian Healthcare