

COLD HOT MEDICATED PATCH 5% MENTHOL- menthol patch
Veridian Healthcare

Theracare 5% Menthol Pain Relief Patch

ACTIVE INGREDIENT

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

PURPOSE

Topical Analgesic

INDICATIONS & USAGE

Temporarily relieves minor pain associated with: ■ arthritis ■ simple backache ■ bursitis ■ tendonitis

■ muscle strains ■ muscle sprains ■ bruises ■ cramps

WARNINGS

For External Use Only.

When using this product

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 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 ■ 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. ■ You experience signs 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 on infants. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away

DOSAGE & ADMINISTRATION

Adults and children 12 years of age and over: Clean and dry affected area, free of lotions, ointments and creams. Carefully remove backing from patch. Apply sticky side of patch to affected area. Do not use more than one patch in an 8 hour period. Repeat as necessary. Maximum 3 patches per day. Discard patch after single use. Reseal pouch after opening.

Children under 12 years of age: consult a physician.

INACTIVE INGREDIENT

dihydroxyaluminium aminoacetate, disodium EDTA, gelatin, glycerin, isopropyl myristate, methyl paraben, polysorbate 80, polyvinyl alcohol, propyl paraben, propylene glycol, sodium carboxy methyl cellulose, sodium polyacrylate, sorbitan monoleate 80, sorbitol, tartaric acid, titanium dioxide, urea, water.



COLD HOT MEDICATED PATCH 5% MENTHOL

menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71101-060
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5 g

Inactive Ingredients

Ingredient Name	Strength
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ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)
POLYVINYL ALCOHOL (UNII: 532B59J990)
WATER (UNII: 059QF0KO0R)
GLYCERIN (UNII: PDC6A3C0OX)
EDETATE DISODIUM (UNII: 7FLD91C86K)
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)
SORBITOL (UNII: 506T60A25R)
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
KAOLIN (UNII: 24H4NWX5CO)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)
TARTARIC ACID (UNII: W4888I119H)
METHYLPARABEN (UNII: A2I8C7HI9T)
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JN12J)
PROPYLPARABEN (UNII: Z8IX2SC1OH)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71101-060-05	5 in 1 BOX	02/01/2025	
1		1 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 Drug	M017	02/01/2025	

Labeler - Veridian Healthcare (830437997)

Establishment

Name	Address	ID/FEI	Business Operations
InterMed Laboratories Private Limited		676244169	manufacture(71101-060)