COLD AND HOT MEDICATED- menthol patch The Mentholatum 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.

Drug Facts

Active ingredient

Menthol 5%

Purpose

Menthol - Topical analgesic

Uses

temporarily relieves minor aches and pains of muscles and joints due to

- arthritis
- simple backache
- strains
- sprains
- bursitis
- tendonitis
- bruises
- cramps

Warnings

For external use only

When using this product

- use only as directed
- avoid contact with eyes or on mucous membranes
- do not apply to wounds or to damaged or very sensitive skin
- do not bandage tightly or use with a heating pad

Stop use and ask a doctor if

- excessive redness or irritation is present
- condition worsens
- pain persist for more than 7 days
- symptoms clear up and occur again within a few days

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

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

Directions

- adults and children 12 years and over: apply patch to affected area as needed but not more than 4 times daily
- children under 12 years: ask a doctor
- for easy application; partially peel back protective film and apply exposed patch to site of pain. Carefully remove remaining film while pressing patch to skin.

Inactive ingredients

carbomer homopolymer, carboxymethylcellulose sodium, castor oil, dihydroxyaluminum aminoacetate, edetate disodium, glycerin, hydroxypropyl cellulose, kaolin, partially neutralized polyacrylate, polyvinyl alcohol, purified water, sorbitol solution, tartaric acid

Package/Label Principal Display Panel

Cut Open Pouch and Remove Pad Reseal Pouch After Opening





Pain Relieving Ointment on a Breathable Adhesive Pad

Lasts up to 8 Hours

- Cold & Hot therapy for pain on a soft and dry medicated patch
- Concentrates medicine at the site of pain
- Holds medicine on painful muscles or joints for long lasting relief

Contains **5** PATCHES in **1** Resealable Pouch 3 15/16" x 7 13/16" (10 cm x 20 cm) each

Package/Label Principal Display Panel

Reseal Pouch After Opening



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Distributed by: Niagara Labs 707 Sterling Drive Orchard Park, NY 14127 Made in Japan

ZA168002

Principal Display Panel

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- . Concentrates medicine at the site of pain
- = Holds medicine on painful muscles or joints for long-lasting relief

Contains 5 PATCHES in 1 Resealable Pouch 31/8"x 45/8" (8 cm x 12 cm) each

Reseal Pouch After Opening



Drug Facts

Active ingredient

Purpose

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ZA157002

COLD AND HOT MEDICATED

menthol patch

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10742-1117	
Route of Administration	TOPICAL			

l	Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength			
	MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	500 mg		

Inactive Ingredients	
Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K6790BS311)	
CASTOR OIL (UNII: D5340Y2I9G)	
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
TARTARIC ACID (UNII: W48881119H)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:10742- 1117-1	1 in 1 CARTON	07/01/2014			
1		5 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	07/01/2014		

COLD AND HOT MEDICATED

menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10742-1118
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	240 mg		

Inactive Ingredients	
Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01Z NK31)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K6790BS311)	
CASTOR OIL (UNII: D5340Y2I9G)	
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
TARTARIC ACID (UNII: W4888I119H)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:10742- 1118-1	1 in 1 CARTON	12/01/2014			
1		5 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	12/01/2014	

Labeler - The Mentholatum Company (002105757)

Registrant - The Mentholatum Company (002105757)

Establishment

Name	Address	ID/FEI	Business Operations
The Mentholatum Company		002105757	label(10742-1117, 10742-1118)

Establishment			
Name	Address	ID/FEI	Business Operations
Teikoku Seiyaku Co., Ltd.		690849997	manufacture(10742-1117, 10742-1118)

Revised: 2/2023 The Mentholatum Company