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

Package/Label Principal Display Panel

Reseal Pouch After Opening

Extra Strength **COLD&HOT**

MEDICATED PATCH Menthol 5%

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

ZA167092

COLD AND HOT MEDICATED

menthol patch

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

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**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: K679OBS311)	
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)	

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: HHT01ZNK31)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
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)	

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