WELLPATCH COOLING PAIN RELIEF- 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

- simple backache
- arthritis
- strains
- sprains

Warnings

For external use only

When using this product

- use only as directed
- avoid contact with eyes and 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

- condition worsens
- excessive redness, irritation, burning, or discomfort of the skin develops
- pain persists for more than 7 days
- symptoms clear up and occur again within a few days

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 to affected area; change patch 1 to 2 times daily
- children under 12 years: ask a doctor
- FOR BEST RESULTS apply to clean, dry skin
- tear open pouch and remove patch; if desired, cut patch to size
- grasp both ends of the patch firmly with thumbs near center
- stretch patch until the backing separates
- remove protective film while applying patch directly to site of pain

Inactive ingredients

carboxymethylcellulose sodium, dihydroxyaluminum aminoacetate, edetate disodium, ethylhexyl acrylate, glycerin, isopropyl myristate, partially neutralized polyacrylate, polyacrylic acid, polymethyl acrylate, polysorbate 80, polyvinyl alcohol, purified water, sodium polyacrylate starch, sorbeth-60 tetraoleate, sorbitan sesquioleate, sorbitol solution, talc, tartaric acid

Questions?

1-877-636-2677 MON - FRI 9AM to 5PM (EST)

www.wellpatch.com

Package/Label Principal Display Panel



Drug Facts

Active ingredient

Purpose ... Topical analgesic

Uses temporarily relieves minor aches and pains of muscles and joints due to ■ simple backache ■ arthritis ■ strains ■ sprains

Warnings

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Questions? 1-877-636-2677 MON-FRI 9 AM to 5 PM (EST) www.wellpatch.com

HOW TO APPLY:

EASY PEEL FILM!

 Grasp both ends of patch firmly, with thumbs near center.



 Stretch patch until the backing separates.



Apply exposed portion of the patch to site of pain.



 Peel off remaining film while gently applying patch.



Distributed

by/Consignor:
The Mentholatum
Company
707 Sterling Drive,
Orchard Park,
NY 14127 USA
Manufactured
by/Consignor:
Mentholatum (China)
Pharmaceuticals
Co.,Ltd.
The Second Industrial
Estates, Sanxiang,
Zhongshan,
Guangdong, China
Made in China

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WELLPATCH COOLING PAIN RELIEF

menthol patch

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10742-8125	
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	50 mg		

Inactive Ingredients	
Ingredient Name	Strength
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K6790BS311)	
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
2-ETHYLHEXYL ACRYLATE (UNII: HR49R9S6XG)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
METHYL ACRYLATE (UNII: WC487PR91H)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
POLYSORBATE 80 (UNII: 60ZP39ZG8H)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
WATER (UNII: 059QF0KO0R)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
SORBITOL (UNII: 506T60A25R)	
TALC (UNII: 7SEV7J4R1U)	
TARTARIC ACID (UNII: W4888I119H)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10742- 8125-1	1 in 1 POUCH; Type 0: Not a Combination Product	02/06/2017	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	02/06/2017		

Labeler - The Mentholatum Company (002105757)

Establishment				
Name	Address	ID/FEI	Business Operations	
The Mentholatum Company		002105757	manufacture(10742-8125)	

Establishment				
Name	Address	ID/FEI	Business Operations	
Mentholatum China Pharmaceuticals Co. Ltd.		420786030	manufacture(10742-8125)	

Revised: 2/2023 The Mentholatum Company