

DOLLAR GENERAL COLD-HOT MEDICATED PATCHES- menthol patch

DOLGENCORP, LLC

Reference Label Set Id: c6e0388b-af9e-4e51-8f94-6788185c31a0

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.

Dollar General Cold-Hot Medicated Patches

ACTIVE INGREDIENT

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

INACTIVE INGREDIENT

Glycerol, Sodium Polyacrylate, Water, Dihydroxyaluminum Aminoacetate, Methylparaben, Propylparaben, Titanium Dioxide, Kaolin, Tween 80, Propylene Glycol, Span 80, Tartaric Acid, PVP, Polyacrylic Acid

KEEP OUT OF REACH OF CHILDREN

If swallowed, get medical help or contact a Poison Control

INDICATIONS & USAGE

Temporarily relieves minor pain associated with: ■ arthritis ■ simple backache ■ bursitis ■ tendonitis ■ muscle strains ■ muscle sprains ■ bruises ■ cramps

WARNINGS

For External Use Only.

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 4 times daily. Reseal pouch after opening.

Children 12 years or younger: Consult a physician.

PURPOSE

Topical Analgesic

When using this product

- Use only as directed ■ Don't bandage tightly or use with heating pad
- Avoid contact with eyes and mucous membranes ■ Don't apply to wounds or damaged skin.

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.

If pregnant or breastfeeding

ask a health professional before use.

DIST. BY

Dolgenercorp, LLC
 100 Mission Ridge
 Goodlettsville, TN 37072



DOLLAR GENERAL COLD-HOT MEDICATED PATCHES			
menthol patch			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-972

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
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM POLYACRYLATE (250000 MW) (UNII: 05I15JN12J)	
DIHYDROXYALUMINUM AMINO ACETATE (UNII: DO250MG0W6)	
WATER (UNII: 059QF0K00R)	
METHYL PARABEN (UNII: A2I8C7H9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
KAOLIN (UNII: 24H4NWX5CO)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
TARTARIC ACID (UNII: W4888119H)	
POVIDONES (UNII: FZ989GH94E)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-972-05	6 in 1 BOX	10/01/2017	
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 not final	part348	10/01/2017	

Labeler - DOLGENCORP, LLC (068331990)

Establishment

Name	Address	ID/FEI	Business Operations
Beijing HKKY Medical		544434817	manufacture(55910-972)

Revised: 10/2017

DOLGENCORP, LLC