

TOPCARE COLD AND HOT MEDICATED- menthol patch
Topco Associates LLC

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.

Topcare Cold & Holt Medicated Patch 5 ct. Large

Active ingredient Purpose

Menthol 5%.....Topical analgesic

Uses

- temporarily relieves minor aches and pains of muscles and joints associated with:
- simple backache
- arthritis
- strains
- bruises
- sprains

Warnings

For external use only

Do not use

- on wounds or damaged skin
- with a heating pad
- on a child under 12 years of age with arthritis-like-conditions

Ask a doctor before use if you have
redness over the affected area

When using this product

- use only as directed
- avoid contact with eyes or mucous membranes
- do not bandage tightly
- discontinue use at least 1 hour before a bath or shower
- do not use immediately after a bath or shower

Stop use and ask a doctor if

- condition worsens or symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days
- excessive skin irritation occurs

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 (1-800-222-1222) right away

Directions

- open pouch and remove patch

- carefully peel off protective backing and apply sticky side to affected area
- adults and children 12 years of age and older:
- do not wear patch for more than 8 hours
- apply to affected area no more than 3 times daily
- children under 12 years of age: consult a doctor

Other information

- store at room temperature 20-25°C (68-77°F)

Inactive ingredients

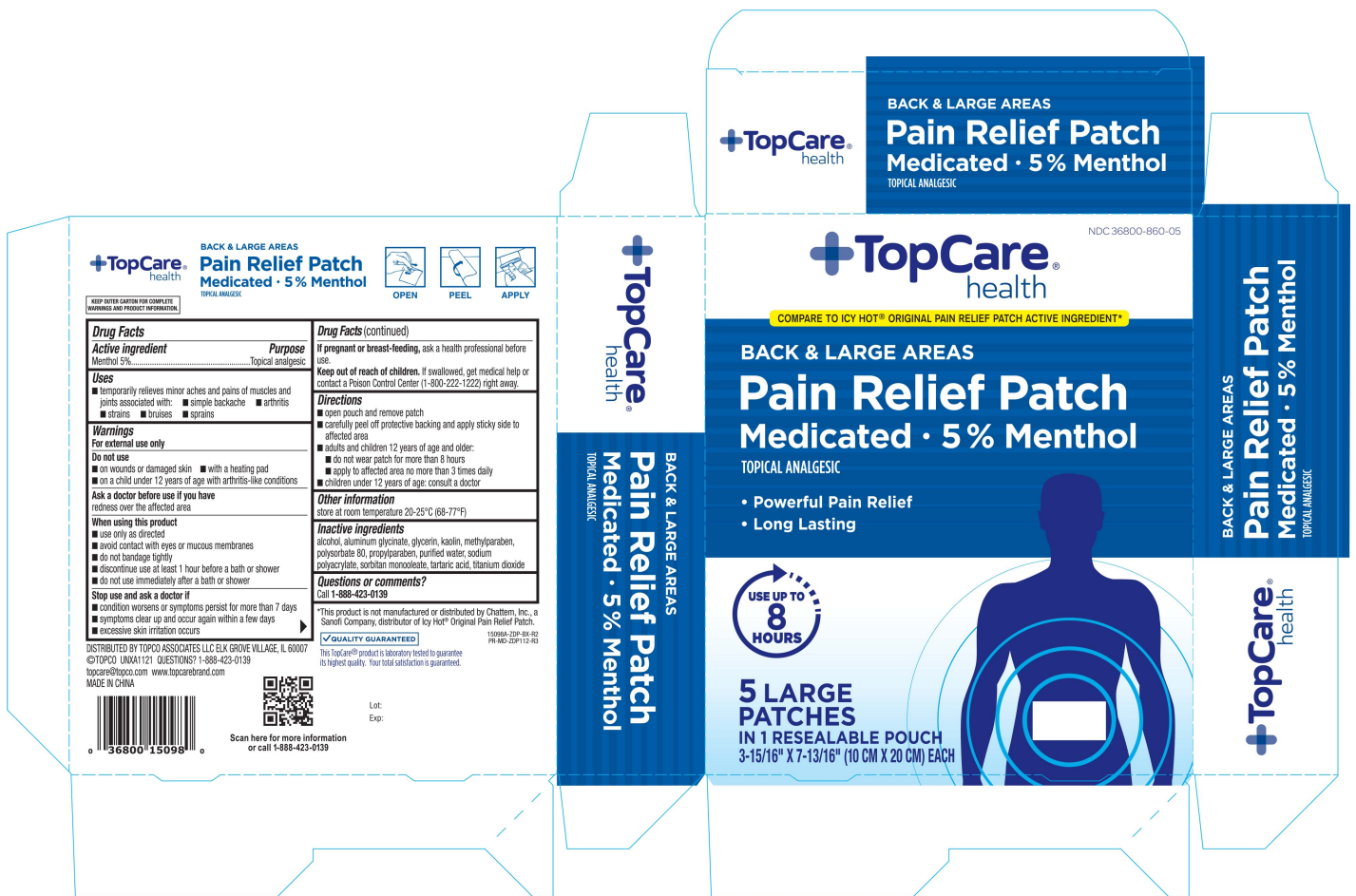
alcohol, aluminum glycinate, glycerin, kaolin, methylparaben, polysorbate 80, propylparaben, purified water, sodium polyacrylate, sorbitan monooleate, tartaric acid, titanium dioxide

Distributed by:

Topco Associates LLC

Elk Grove Village, IL 60007

Made in China



TOPCARE COLD AND HOT MEDICATED
 menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-860	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)		MENTHOL	50 mg	
Inactive Ingredients				
Ingredient Name			Strength	
METHYLPARABEN (UNII: A2I8C7HI9T)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
PROPYPARABEN (UNII: Z8IX2SC1OH)				
ALCOHOL (UNII: 3K9958V90M)				
KAOLIN (UNII: 24H4NWX5CO)				
TARTARIC ACID (UNII: W4888I119H)				
DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS (UNII: 1K713C615K)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
WATER (UNII: 059QF0KO0R)				
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)				
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-860-05	5 in 1 BOX	04/23/2019	
1		1 in 1 PATCH; 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	04/23/2019		

Labeler - Topco Associates LLC (006935977)