

## **HOT AND COLD MEDICATED PATCH- menthol patch**

**Chain Drug Consortium, 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.*

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### **Hot and Cold Medicated Patch**

#### **ACTIVE INGREDIENT**

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

#### **INACTIVE INGREDIENT**

Glycerin, Sodium Polyacrylate, Water, Dihydroxyaluminum Aminoacetate, Methylparaben, Propylparaben, Titanium Dioxide, Kaolin, Polysorbate 80, Propylene Glycol, 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.

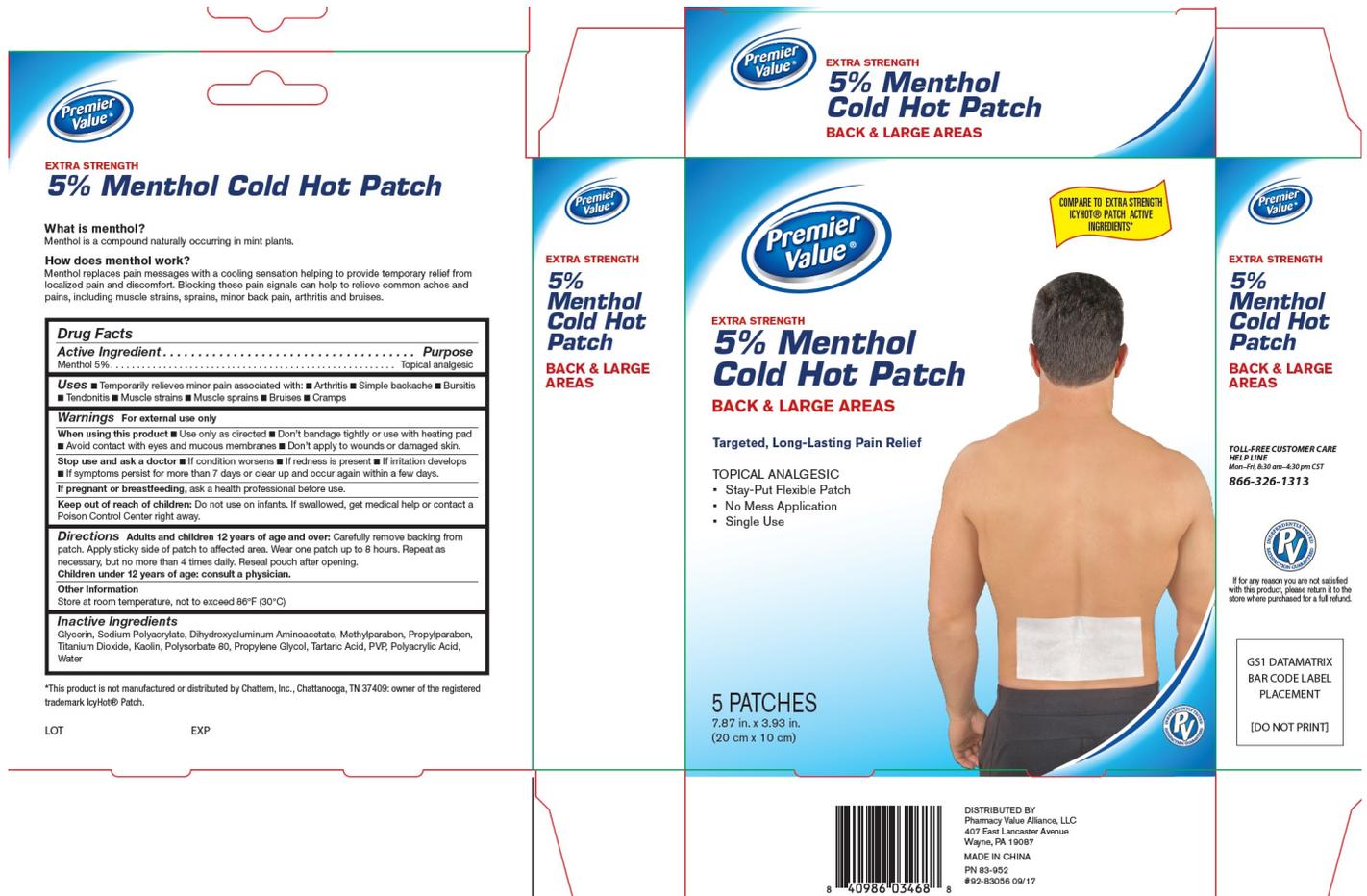
#### **Stop use and ask a doctor**

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  
 Pharmacy Value Alliance, LLC  
 407 East Lancaster Avenue  
 Wayne, PA 19087



HOT AND COLD MEDICATED PATCH			
menthol patch			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:680 16-068
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>

MENTHOL (UNII: L7T10EP3A) (MENTHOL - UNII:L7T10EP3A)	MENTHOL	5
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### Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM POLYACRYLATE (250000 MW) (UNII: 05115JN12J)	
DIHYDROXYALUMINUM AMINO ACETATE (UNII: DO250MG0W6)	
WATER (UNII: 059QF0KO0R)	
METHYL PARABEN (UNII: A218C7H9T)	
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:68016-068-05	5 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** - Chain Drug Consortium, LLC (101668460)

### Establishment

Name	Address	ID/FEI	Business Operations
Beijing HKKY Medical		544434817	manufacture(68016-068)

Revised: 10/2017

Chain Drug Consortium, LLC