

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

**Simple Diagnostics, Inc.**

*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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### **cold & hot patch**

#### **Active Ingredient**

Menthol 5.00%.

#### **Purpose**

Topical analgesic

#### **Use**

temporarily relieves minor aches and pains of muscles and joints due to  
.arthritis .simple backache .sprains . strains  
.bursitis .tendonitis . Bruises . Cramps

#### **Warning**

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 damaged skin. do not bandage tightly or use a heating pad

Stop use and ask doctor if

.excessive redness or irritation is present

.condition worsens

.pain persists 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.

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#### **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: grasp both ends of pad firmly, pull at both ends. Stretch pad until the backing separates.

Remove protective film while applying pad directly to site of pain.

#### **Inactive Ingredients**

Acrylic Acid, Aluminum Hydroxide, Carmellose Sodium, 2 Ethylhexyl Acrylate, Glycerin, Isopropyl Myristate, Methyl Acrylate, Nonoxynol 30, Polyacrylate, Polyacrylic Acid, Polysorbate 80, Sorbitan Sesquioleate, Starch, Talc, Tartaric

# Drug Facts

## Active ingredient

Menthol 5% .....Topical analgesic

## Purpose

### USES

for the temporary relief of minor aches and pains associated with:

- simple backache
- muscle strains
- muscle sprains
- cramps
- bursitis
- arthritis
- bruises

### Warnings

**For external use only**

**When using this product** ■ use only as directed ■ do not apply to wounds, damaged, or sensitive skin ■ do not bandage tightly or use with a heating pad ■ avoid contact with eyes and mucous membranes

#### Stop use and ask doctor if

- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days
- redness is present
- skin irritation develops

**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 of age and older**

- partially peel back protective film and apply exposed patch to site of pain for up to 8 hours
- carefully remove remaining film while pressing patch to skin for secure adhesion
- repeat as necessary, but not more than 3 to 4 times daily

**children under 12 years of age** consult a doctor

**Other information** store at 68° to 77°F (20° to 25°C)

**Inactive ingredients** acrylic acid, aluminum hydroxide, carmellose sodium, 2-ethylhexyl acrylate, glycerin, isopropyl myristate, methyl acrylate, nonoxynol-30, polyacrylate, polyacrylic acid, polysorbate 80, sorbitan sesquioleate, starch, talc, tartaric acid, titanium dioxide, water(245-114).

**Release liner** polypropylene, **Non-woven material** polyester non-woven fabric

## COLD HOT PATCH

menthol patch

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:62379-001
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
ACRYLIC ACID (UNII: J94PBK7X8S)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
2-ETHYLHEXYL ACRYLATE (UNII: HR49R9S6XG)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
METHYL ACRYLATE (UNII: WC487PR91H)	
NONOXYNOL-30 (UNII: JJX07DG188)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
STARCH, POTATO (UNII: 8I089SAH3T)	
TALC (UNII: 7SEV7J4R1U)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

### Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62379-001-35	4 in 1 CARTON		
1		12 in 1 PACKAGE		
1		1 in 1 BOX		
1		2 in 1 BAG		
1	NDC:62379-001-25	.408 g in 1 PATCH		

# Drug Facts

## Active ingredient

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## Purpose

**USES** for the temporary relief of minor aches and pains associated with:

■ simple backache ■ muscle strains ■ muscle sprains ■ cramps ■ bursitis ■ arthritis ■ bruises

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**Release liner** polypropylene, **Non-woven material** polyester non-woven fabric

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	02/23/2015	

**Labeler** - Simple Diagnostics, Inc. (004135503)

Revised: 2/2015

Simple Diagnostics, Inc.