

**COOL N HEAT PATCH FOR BACK EXTRA STRENGTH- menthol patch
Walgreen Co.**

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.

Menthol 5% (Topical Analgesic)

Active Ingredient

Menthol 5%

Purpose

Topical Analgesic

Uses

Temporarily relieves minor pain associated with:

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

Warnings

- For external use only
- If pregnant or breast-feeding, ask a health professional before use.

When using this product

- use only as directed
- do not bandage tightly or use with a heating pad
- avoid contact with eyes and mucous membranes
- do not apply to wounds or damaged skin

Stop use and ask a doctor if

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

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

- peel off protective backing and apply sticky side to affected area
- carefully remove backing from patch
- apply one patch to affected area
- repeat as necessary, but no more than 4 times daily

Children under 12 years of age consult a doctor

Other information

- store at room temperature

Inactive ingredients

aloe barbadensis leaf juice, alumina magnesium metasilicate, aluminum hydroxide, BHT, castor oil, disodium EDTA, gelatin, glycerin, isopropyl myristate, kaolin, methylparaben, PEG-4 stearate, polysorbate 80, polyvinyl alcohol, purified water, PVP, sodium polyacrylate, tartaric acid, titanium dioxide, tocopherol acetate

Questions or comments?

1-800-WALGREENS (1-800-925-4733)

Drug Facts

Active ingredient Menthol 5% / Topical Analgesic

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†Walgreens Pharmacist Survey Study, November 2012
 ††This product is not manufactured or distributed by Chalmers, Inc., distributor of Extra Strength Icy Hot Patch.
 TBM 652728
 ORG 0713-F3
 DISTR BUTD BY: WALGREEN CO.



usa3425



RESEALABLE



WALGREENS PHARMACIST RECOMMENDED[†]

EXTRA STRENGTH

Cool 'n Heat Patch

Menthol 5% / Topical Analgesic

- Pain relieving ointment on a breathable, self-adhering patch
- Long-lasting relief

5 PATCHES IN ONE
 RESEALABLE POUCH
 3.9 IN X 7.9 IN (10 cm x 20 cm) EACH

Compare to Extra Strength Icy Hot[®] Patch active ingredient^{††}

COOL N HEAT PATCH FOR BACK EXTRA STRENGTH

menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-0152
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	.05 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Aloe Vera Leaf (UNII: ZY81Z83H0X)	
Aluminum Hydroxide (UNII: 5QB0T2IUN0)	
Edetate Disodium (UNII: 7FLD91C86K)	
Gelatin (UNII: 2G86QN327L)	
Kaolin (UNII: 24H4NWX5CO)	
Methylparaben (UNII: A2I8C7HI9T)	
Glycerin (UNII: PDC6A3C0OX)	
Titanium Dioxide (UNII: 15FIX9V2JP)	
Isopropyl Myristate (UNII: 0RE8K4LNJS)	
Water (UNII: 059QF0KO0R)	
PEG-4 Stearate (UNII: J33E8608YN)	
Polyvinyl Alcohol (UNII: 532B59J990)	
Polysorbate 80 (UNII: 6OZP39ZG8H)	
Alpha-Tocopherol Acetate (UNII: 9E8X80D2L0)	
Silodrate (UNII: 9T3UU8T0QK)	
Castor Oil (UNII: D5340Y2I9G)	
Tartaric Acid (UNII: W4888I119H)	
Butylated Hydroxytoluene (UNII: 1P9D0Z171K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0152-01	5 in 1 BOX		
1		1 g in 1 PATCH		
2	NDC:0363-0152-02	3 in 1 BOX		
2		1 g in 1 PATCH		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	08/15/2013	

Labeler - Walgreen Co. (008965063)

Revised: 10/2013

Walgreen Co.