

ICY HOT MEDICATED ROLL, MEDIUM- menthol patch

ICY HOT MEDICATED ROLL, LARGE- menthol patch

Nichiban Company Limited

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.

Drug Facts

Active ingredient

Menthol 7.5%

Purpose

Topical analgesic

Uses

temporarily relieves minor pain associated with:

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

Warnings:

For external use only

When using this product

- use only as directed
- do not bandage tightly or use with a heating pad
- do not overwrap or wrap strips over themselves
- do not wrap around neck
- do not apply over large areas of the body or apply in strips longer than 6 inches
- avoid contact with eyes and mucous membranes
- do not apply to wounds or damaged, broken or irritated skin

Stop use and ask a doctor if:

- condition worsens
- redness is present
- irritation develops
- symptoms persist for more than 7 days or 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.

Directions:**adults and children over 12 years:**

- tear or cut roll to desired size
- carefully remove backing from one end of strip and place on affected area
- remove remaining backing and press into place
- wear Icy Hot Medicated Roll for up to 8 hours
- repeat as necessary, but no more than 3 to 4 times daily

children 12 years or younger: ask a doctor

Keep carton as it contains important information for usage of this product.

Distributed by Chattem, Inc.

P.O. Box 2219

Chattanooga, TN 37409-0219 USA

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MADE IN JAPAN

[NDC Code]

Principal Display Panel - Medium Roll, Pouch

Reseal Pouch After Opening

ICY HOT® MEDICATED ROLL

Menthol 7.5%

CUSTOMIZED PAIN RELIEF

- **Tear** or **Cut** to Any Length
- Lasts up to **8 Hours**
- Comfortable, Flexible, **Stays in Place**

EXTRA STRENGTH**MEDIUM - 2"**

Pain Relieving Ointment on Breathable, Flexible Fabric

2" x 60" (5 cm x 150 cm)



Medium Roll Pouch

Principal Display Panel - Large Roll, Pouch

Reseal Pouch After Opening

ICY HOT® MEDICATED ROLL

Menthol 7.5%

CUSTOMIZED PAIN RELIEF

- **Tear** or **Cut** to Any Length
- Lasts up to **8 Hours**
- Comfortable, Flexible, **Stays in Place**

EXTRA STRENGTH

LARGE - 3"

Pain Relieving Ointment on Breathable, Flexible Fabric

3" x 43" (7.5 cm x 110 cm)



Large Roll Pouch

ICY HOT MEDICATED ROLL, MEDIUM

menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:440 14-085
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)		MENTHOL	787.5 mg

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:440 14-085-01	1 in 1 POUCH		
2	NDC:440 14-085-03	170 in 1 BOX		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/01/2009	

ICY HOT MEDICATED ROLL, LARGE				
menthol patch				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:440 14-086	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)		MENTHOL	866.25 mg	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:440 14-086-07	1 in 1 POUCH		
2	NDC:440 14-086-02	150 in 1 BOX		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	04/01/2009		

Labeler - Nichiban Company Limited (690544325)

Establishment			
Name	Address	ID/FEI	Business Operations
Nichiban Company Limited		690544325	ANALYSIS, MANUFACTURE

