ICY HOT ARM NECK LEG AND SMALL AREAS- menthol patch ICY HOT BACK AND LARGE AREAS- menthol patch ICY HOT XL BACK AND LARGE AREAS- menthol patch Chattem, Inc.

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Icy Hot - Patch

Icy Hot® - Medicated Patch
ARM, NECK & LEG & SMALL AREAS

#### **Active Ingredient**

Menthol 5%

#### **Purpose**

Topical analgesic

#### Uses

- temporarily relieves minor pain associated with:
  - arthritis
  - simple backache
  - bursitis
  - tendonitis
  - muscle strains
  - sprains
  - bruises
  - cramps

#### Warnings

#### For external use only

#### When using this product

- use only as directed. Read and follow all directions and warnings on this carton.
- avoid contact with eyes and mucous membranes
- rare cases of serious burns have been reported with products of this type
- do not apply to wounds or damaged skin, broken or irritated skin
- do not bandage tightly or apply local heat (such as heating pads) to the area of use
- a transient burning sensation may occur upon application but generally disappears in several days

#### 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
- you experience signs of skin injury, such as pain, swelling, or blistering where the product was applied

#### 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.

- remove backing from patch by firmly grasping both ends and gently pulling until backing separates in middle
- carefully remove smaller portion of backing from patch and apply exposed portion of patch to affected area
- once exposed portion of patch is positioned, carefully remove remaining backing to completely apply patch to affected area
- apply one patch to affected area
- wear one Icy Hot Patch up to 8 hours
- repeat as necessary, but no more than 3 times daily

#### children 12 years or younger: ask a doctor

#### **Inactive Ingredients**

aluminum hydroxide, cellulose gum, glycerin, isopropyl myristate, methyl acrylate/2-ethylhexyl acrylate copolymer, nonoxynol-30, polyacrylic acid, polysorbate 80, sodium polyacrylate, sorbitan sesquioleate, starch/acrylic acid graft copolymer sodium salt, talc, tartaric acid, titanium dioxide, water

KEEP CARTON AS IT CONTAINS IMPORTANT INFORMATION FOR USAGE OF THE PRODUCT.

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Icy Hot® - Medicated Patch
BACK & LARGE AREAS

#### **Active Ingredient**

Menthol 5%

#### **Purpose**

Topical analgesic

#### Uses

- temporarily relieves minor pain associated with:
  - arthritis
  - simple backache
  - bursitis
  - tendonitis
  - muscle strains
  - sprains
  - bruises
  - cramps

#### Warnings

#### For external use only

#### When using this product

- use only as directed. Read and follow all directions and warnings on this carton.
- avoid contact with eyes and mucous membranes
- rare cases of serious burns have been reported with products of this type
- do not apply to wounds or damaged skin, broken or irritated skin
- do not bandage tightly or apply local heat (such as heating pads) to the area of use
- a transient burning sensation may occur upon application but generally disappears in several days

#### 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
- you experience signs of skin injury, such as pain, swelling, or blistering where the product was applied

#### 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.

- remove backing from patch by firmly grasping both ends and gently pulling until backing separates in middle
- carefully remove smaller portion of backing from patch and apply exposed portion of patch to affected area
- once exposed portion of patch is positioned, carefully remove remaining backing to completely apply patch to affected area
- apply one patch to affected area
- wear one Icy Hot Patch up to 8 hours
- repeat as necessary, but no more than 3 times daily

children 12 years or younger: ask a doctor

#### **Inactive Ingredients**

aluminum hydroxide, cellulose gum, glycerin, isopropyl myristate, methyl acrylate/2ethylhexyl acrylate copolymer, nonoxynol-30, polyacrylic acid, polysorbate 80, sodium polyacrylate, sorbitan sesquioleate, starch/acrylic acid graft copolymer sodium salt, talc, tartaric acid, titanium dioxide, water

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Icy Hot® - Medicated Patch
XL BACK & LARGE AREAS

#### **Active Ingredient**

Menthol 5%

#### **Purpose**

Topical analgesic

#### Uses

- temporarily relieves minor pain associated with:
  - arthritis
  - simple backache

- bursitis
- tendonitis
- muscle strains
- sprains
- bruises
- cramps

#### Warnings

#### For external use only

#### When using this product

- use only as directed. Read and follow all directions and warnings on this carton.
- avoid contact with eyes and mucous membranes
- rare cases of serious burns have been reported with products of this type
- do not apply to wounds or damaged skin, broken or irritated skin
- do not bandage tightly or apply local heat (such as heating pads) to the area of use
- a transient burning sensation may occur upon application but generally disappears in several days

#### 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
- you experience signs of skin injury, such as pain, swelling, or blistering where the product was applied

#### 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.

- remove backing from patch by firmly grasping both ends and gently pulling until backing separates in middle
- carefully remove smaller portion of backing from patch and apply exposed portion of patch to affected area
- once exposed portion of patch is positioned, carefully remove remaining backing to completely apply patch to affected area
- apply one patch to affected area
- wear one Icy Hot Patch up to 8 hours
- repeat as necessary, but no more than 3 times daily

#### children 12 years or younger: ask a doctor

#### **Inactive Ingredients**

aluminum hydroxide, cellulose gum, glycerin, isopropyl myristate, methyl acrylate/2-ethylhexyl acrylate copolymer, nonoxynol-30, polyacrylic acid, polysorbate 80, sodium polyacrylate, sorbitan sesquioleate, starch/acrylic acid graft copolymer sodium salt, talc, tartaric acid, titanium dioxide, water

KEEP CARTON AS IT CONTAINS IMPORTANT INFORMATION FOR USAGE OF THE PRODUCT.

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#### Principal Display Panel

ICY HOT®
ORIGINAL
Pain Relief Patch
Menthol 5%
ICY to DULL, HOT to RELAX
Wear for up to 8 Hours
Small Patch
3-1/8" x 4-5/8" (8 cm x 12 cm) each
ARM. NECK & LEG PATCH
Contains 5 Patches in 1 Resealable Pouch



#### Principal Display Panel

ICY HOT®
ORIGINAL
Pain Relief Patch
Menthol 5%
ICY to DULL, HOT to RELAX
Wear for up to 8 Hours
LARGE PATCH
3-15/16" x 7-13/16" (10 cm x 20 cm) each
Contains 5 Patches In 1 Resealable Pouch



#### Principal Display Panel

ICY HOT®
ORIGINAL
Pain Relief Patch
Menthol 5%
ICY to DULL, HOT to RELAX
Wear for up to 8 Hours
XL PATCH
5-1/2" x 9-3/4" (14 cm x 25 cm) each
Contains 3 Patches In 1 Resealable Pouch



#### **Principal Display Panel**

ICY HOT®
ORIGINAL
Pain Relief Patch

#### Cut Open Pouch and Remove Pad



For easy removal of embossed backing:







#### **Drug Facts**

#### Active ingredient

Menthol 5%.

Purpose

Topical analgesic

USes temporarily relieves minor pain associated with: marthritis simple backache bursitis tendonitis muscle strains sprains bruises cramps

#### Warnings

For external use only

When using this product use only as directed. Read and follow all directions and warnings on this label.

- avoid contact with eyes and mucous membranes. arrae cases of serious burns have been reported with products of this type
- . do not apply to wounds or damaged, broken or irritated skin
- m do not bandage rightly or apply local heat (such as heating pads) to the area of use
- a transient burning sensation may occur upon application but generally disappears in several days

Stop use and ask a doctor if me condition worsens me redness is present me irritation develops

- symptoms persist for more than 7 days or clear up and occur again within a few days
- you experience signs of skin injury, such as pain, swelling, or blistering where the product was applied

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:

- remove backing from patch by firmly grasping both ends and gently pulling until backing separates in middle
- a carefully remove smaller portion of backing from patch and apply exposed portion of patch to affected area
- once exposed postion of patch is positioned, carefully remove remaining backing to completely apply patch to affected area
- wear one ky Hot patch for up to 8 hours
   repeat as necessary, but no more than 3 times daily

children 12 years or younger: ask a doctor

Inactive ingredients

aluminum hydroxide, cellulose gum, glycerin, isopropyl myristate, methyl acrylate/2-ethylhexyl acrylate copolymer, noncoynol-30, polyacrylic acid, polysorbate 80, sodium polyacrylate, sorbiran sesquioleate, starch/acrylic acid graft copolymer sodium salt, talc, tartaric acid, titanium dioxide, water



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Principal Display Panel

ICY HOT® **ORIGINAL Pain Relief Patch** Menthol 5%

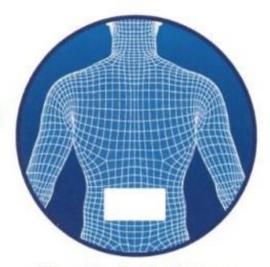


## LARGE PATCH

# FEEL IT WORKING INSTANTLY

- ▶ Powerful Targeted Relief
- ▶ Icy to Dull, Hot to Relax
- ▶ Comfortable Fabric
- ► Stays in Place

Contains 1 Patch 3-15/16" x 7-13/16" (10 cm x 20 cm)



Wear For Up To 8 Hours

#### ICY HOT ARM NECK LEG AND SMALL AREAS

menthol patch

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41167-0084	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	205.50 mg	

<b>Inactive Ingredients</b>
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Ingredient Name	Strength
ACRYLIC ACID (UNII: J94PBK7X8S)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K6790BS311)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
METHYL ACRYLATE (UNII: WC487PR91H)	
ETHYLHEXYL ACETATE (UNII: 2C7K8OA8SB)	
NONOXYNOL-30 (UNII: JJX07DG188)	
POLYSORBATE 80 (UNII: 60ZP39ZG8H)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
TALC (UNII: 7SEV7J4R1U)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41167- 0084-1	1 in 1 CARTON	11/01/2000	
1		5 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information			
Marketing Application Number or Monograph Marketing Start Marketing End Category Citation Date Date			
OTC Monograph Drug	M017	11/01/2000	

## **ICY HOT BACK AND LARGE AREAS**

menthol patch

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41167-0843	
Route of Administration	TOPICAL			

Strength Strength
428.50 mg

## **Inactive Ingredients**

Ingredient Name	Strength
ACRYLIC ACID (UNII: J94PBK7X8S)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K6790BS311)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
METHYL ACRYLATE (UNII: WC487PR91H)	
ETHYLHEXYL ACETATE (UNII: 2C7K8OA8SB)	
NONOXYNOL-30 (UNII: JJX07DG188)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
TALC (UNII: 7SEV7J4R1U)	
TARTARIC ACID (UNII: W48881119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41167- 0843-1	1 in 1 CARTON	03/01/2003	
1		5 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:41167- 0843-7	3 in 1 CARTON	03/01/2003	
2		5 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:41167- 0843-2	1 in 1 CARTON	03/01/2003	
3		6 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 Drug	M017	03/01/2003	

## ICY HOT XL BACK AND LARGE AREAS

menthol patch

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41167-0847
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	750.00 mg

Inactive Ingredients	
Ingredient Name	Strength
ACRYLIC ACID (UNII: J94PBK7X8S)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K6790BS311)	
ETHYLHEXYL ACETATE (UNII: 2C7K8OA8SB)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: ORE8K4LNJS)	
METHYL ACRYLATE (UNII: WC487PR91H)	
NONOXYNOL-30 (UNII: JJX07DG188)	
POLYSORBATE 80 (UNII: 60ZP39ZG8H)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
TALC (UNII: 7SEV7J4R1U)	
TARTARIC ACID (UNII: W48881119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41167- 0847-1	1 in 1 CARTON	12/01/2007	
1		3 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:41167- 0847-2	1 in 1 CARTON	03/10/2017	
2		4 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information				
Marketing Application Number or Monograph Marketing Start Marketing End Category Citation Date Date				
OTC Monograph Drug	M017	12/01/2007		

## **ICY HOT BACK AND LARGE AREAS**

menthol patch

### **Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41167-0073
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	428.50 mg

Inactive Ingredients		
Ingredient Name	Strength	
ACRYLIC ACID (UNII: J94PBK7X8S)		
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)		
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K6790BS311)		
ETHYLHEXYL ACETATE (UNII: 2C7K8OA8SB)		
GLYCERIN (UNII: PDC6A3C0OX)		
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)		
METHYL ACRYLATE (UNII: WC487PR91H)		
NONOXYNOL-30 (UNII: JJX07DG188)		
POLYSORBATE 80 (UNII: 60ZP39ZG8H)		
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)		
TALC (UNII: 7SEV7J4R1U)		
TARTARIC ACID (UNII: W4888I119H)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
WATER (UNII: 059QF0KO0R)		
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)		
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)		

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41167- 0073-8	2 in 1 CARTON	03/01/2003	
1		5 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information				
Marketing Application Number or Monograph Marketing Start Marketing End Category Citation Date Date				
OTC Monograph Drug	M017	03/01/2003		

## **ICY HOT BACK AND LARGE AREAS**

menthol patch

#### **Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41167-0083
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	428.50 mg

Inactive Ingredients	
Ingredient Name	Strength
ACRYLIC ACID (UNII: J94PBK7X8S)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K6790BS311)	
ETHYLHEXYL ACETATE (UNII: 2C7K8OA8SB)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
METHYL ACRYLATE (UNII: WC487PR91H)	
NONOXYNOL-30 (UNII: JJX07DG188)	
POLYSORBATE 80 (UNII: 60ZP39ZG8H)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
TALC (UNII: 7SEV7J4R1U)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	

Packaging					
#	tem Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:41167- 0083-2	1 in 1 POUCH; Type 0: Not a Combination Product	03/01/2003		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M017	03/01/2003		

## Labeler - Chattem, Inc. (003336013)

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