ICY HOT MEDICATED- menthol patch
ICY HOT MEDICATED, BACK- menthol patch
ICY HOT MEDICATED, XL- menthol patch
ICY HOT MEDICATED, ADVANCED RELIEF- menthol patch
Lead Chemical Co., Ltd.

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#### Icy Hot® Medicated Patch

#### **Active Ingredient**

<u>Icy Hot Arm, Neck and Leg Patches; Icy Hot Back Patches; and Icy Hot XL Patches</u> Menthol 5%

<u>Icy Hot Advanced Relief Patches</u>

Menthol 7.5%

#### **Purpose**

Topical analgesic

#### Uses

<u>Icy Hot Arm, Neck and Leg Patches; Icy Hot Back Patches; and Icy Hot XL Patches</u> temporarily relieves minor pain associated with:

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

#### Icy Hot Advanced Relief Patches

temporarily relieves minor aches and pains of muscles and joints associated with:

- arthritis
- simple backache
- strains
- sprains
- bruises

#### Warnings

For external use only

#### Do not use

#### **Icy Hot Advanced Relief Patches**

- on wounds or on irritated or damaged skin
- with a heating pad

#### When using this product

<u>Icy Hot Arm, Neck and Leg Patches; Icy Hot Back Patches; and Icy Hot XL Patches</u>

- use only as directed. Read and follow all directions and warnings on this label.
- 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, 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

#### **Icy Hot Advanced Relief Patches**

- use only as directed
- do not bandage tightly
- avoid contact with eyes and mucous membranes
- do not expose the area to local heat or to direct sunlight
- rare cases of serious burns have been reported with products of this type
- a transient burning sensation may occur upon application but generally disappears in several days
- avoid applying into skin folds

#### Stop use and ask a doctor if

<u>Icy Hot Arm, Neck and Leg Patches; Icy Hot Back Patches; and Icy Hot XL Patches</u>

- 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

#### **Icy Hot Advanced Relief Patches**

- condition worsens or symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days
- redness is present or excessive skin irritation occurs
- you experience severe burning 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**

<u>Icy Hot Arm, Neck and Leg Patches; Icy Hot Back Patches; and Icy Hot XL Patches</u>

#### 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
- wear one Icy 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

**Icy Hot Advanced Relief Patches** 

#### adults and children 12 years of age and older:

- clean and dry affected area
- gently fold the patch in half to remove center section of film backing. Apply the exposed adhesive portion to the site of pain.
- remove remaining film backing from both sides and finish applying to skin
- apply to affected area not more than 3 to 4 times daily
- wash hands after applying or removing patch. Throw away the patch by folding sticky ends together.

#### children under 12 years of age: ask a doctor

#### **Inactive ingredients**

<u>Icy Hot Arm, Neck and Leg Patches; Icy Hot Back Patches; and Icy Hot XL Patches</u>

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

**Icy Hot Advanced Relief Patches** 

glyceryl hydrogenated rosinate, mineral oil, polyisobutene, styrene/isoprene copolymer

#### Principal Display Panel - Arm, Neck & Leg Pouch

ICY HOT® ORIGINAL Pain Relief Patch

ARM, NECK & LEG PATCH

FEEL IT WORKING INSTANTLY

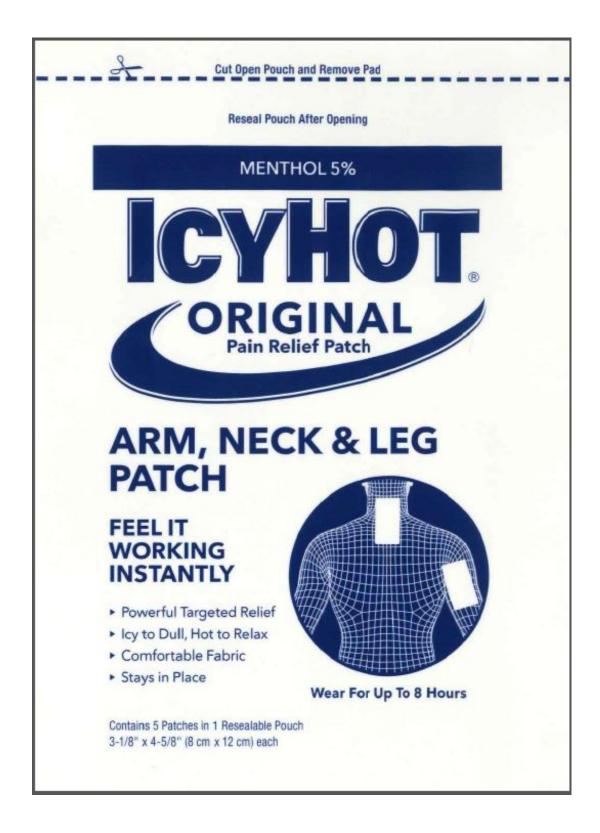
- > Powerful Targeted Relief
- > Icy to Dull, Hot to Relax
- > Comfortable Fabric
- > Stays in Place

#### Wear For Up To 8 Hours

Contains 5 Patches in 1 Resealable Pouch 3-1/8" x 4-5/8" (8 cm x 12 cm) each

#### **CHATTEM**®

A SANOFI COMPANY Dist. by Chattem, Inc., a Sanofi Company P.O. Box 2219 Chattanooga, TN 37409-0219 USA © 2020 www.icyhot.com



Pouch Label - Arm, Neck, & Leg

Principal Display Panel - Extra Strength Back and Large Areas ICY  $HOT^{\circledR}$ 

MEDICATED PATCH Menthol 5% BONUS 20% MORE! one free patch inside

# TARGETED NO MESS RELIEF

- **Stops Pain** at the Source
- Lasts up to 8 Hours
- Comfortable Fabric **Stays in Place**

Pain Relieving Ointment on a Breathable Adhesive Pad

#### EXTRA STRENGTH BACK and Large Areas

Contains **6** Patches in 1 Resealable Pouch 3-15/16" x 7-13/16" (10 cm x 20 cm) each

#### **CHATTEM**®

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Pouch Label - Back and Large Areas - Bonus

#### **Principal Display Panel - XL Back**

**MENTHOL 5%** 

ICY HOT®
ORIGINAL
Pain Relief Patch

**XL PATCH** 

FEEL IT WORKING INSTANTLY

> Powerful Targeted Relief

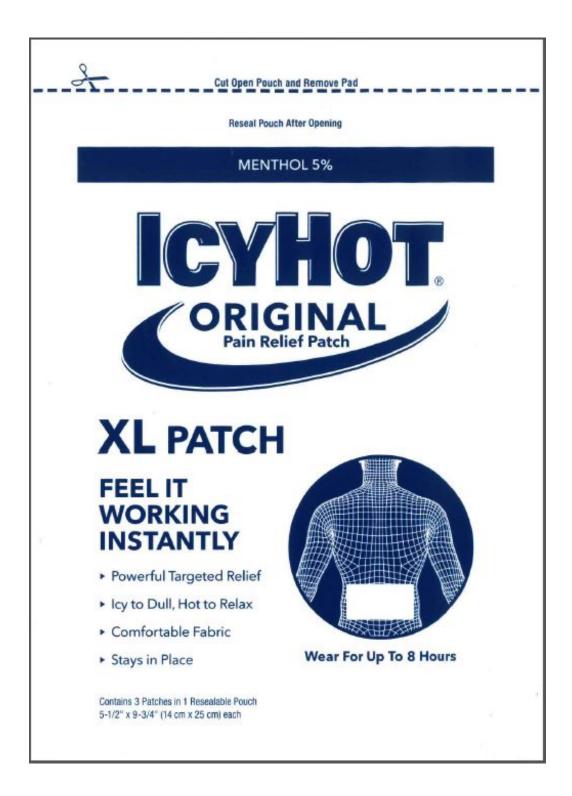
- > Icy to Dull, Hot to Relax
- > Comfortable Fabric
- > Stays in Place

#### **Wear For Up To 8 Hours**

Contains 3 Patches in 1 Resealable Pouch 5-1/2" x 9-3/4" (14 cm x 25 cm) each

#### **CHATTEM**®

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Pouch Label - XL Back

#### Principal Display Panel - Extra Strength XL Back and Large Areas

**MENTHOL 5%** 

ICY HOT®
ORIGINAL
Pain Relief Patch
XL PATCH

#### FEEL IT WORKING INSTANTLY

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

#### **Wear For Up To 8 Hours**

Contains 4 Patches in 1 Resealable Pouch 5-1/2" x 9-3/4" (14 cm x 25 cm) each

#### **CHATTEM**®

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Pouch Label - XL Back - Bonus

#### Principal Display Panel - Advanced Pain Relief Patch

MENTHOL 7.5%

ICY HOT® ADVANCED Pain Relief Patch

# LARGE PATCH MORE PAIN FIGHTING INGREDIENTS\*

- > Fast Acting Powerful Relief
- > Comfortable Fabric
- > Stays in Place

#### Wear For Up To 8 Hours

Contains 5 Patches in 1 Resealable Pouch 3-15/16" x 5-1/2" (10 cm x 14 cm) each

\*Per same size patch vs Icy Hot® original strength patch

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Chattanooga, TN 37409-0219 USA

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Pouch Label - Advanced Pain Relief Patch

# menthol patch Product Information Product Type HUMAN OTC DRUG Item Code (Source) Route of Administration TOPICAL Active Ingredient/Active Moiety

Ingredient Name	<b>Basis of Strength</b>	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	205.5 mg

Inactive Ingredients	
Ingredient Name	Strength
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K6790BS311)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
NONOXYNOL-30 (UNII: JJX07DG188)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	
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:62168- 0084-3	270 in 1 BOX	06/09/2021	06/30/2026	
1		5 in 1 POUCH; Type 0: Not a Combination Product			
2	NDC:62168- 0084-4	160 in 1 CARTON	12/08/2023		
2		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	505G(a)(3)	11/01/2000		

### ICY HOT MEDICATED, BACK

menthol patch

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62168-0843
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	<b>Basis of Strength</b>	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	428.5 mg

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

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62168- 0843-9	80 in 1 CARTON	10/16/2017	03/31/2024
1		6 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information			
Marketing Application Number or Monograph Marketing Start Marketing En Category Citation Date Date			
OTC Monograph Drug	505G(a)(3)	03/01/2003	03/31/2024

## ICY HOT MEDICATED, XL

menthol patch

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62168-0847
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	<b>Basis of Strength</b>	Strength

Inactive Ingredients	
Ingredient Name	Strength
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K6790BS311)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
NONOXYNOL-30 (UNII: JJX07DG188)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
POLYSORBATE 80 (UNII: 60ZP39ZG8H)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05115JN12J)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
TALC (UNII: 7SEV7J4R1U)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2IP)	

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62168- 0847-4	100 in 1 BOX	06/01/2011	03/31/2024
1	NDC:62168- 0847-3	4 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:62168- 0847-5	120 in 1 CARTON	05/17/2021	07/31/2026
2		3 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:62168- 0847-6	100 in 1 BOX	05/12/2021	01/31/2025
3		4 in 1 POUCH; Type 0: Not a Combination Product		
4	NDC:62168- 0847-7	100 in 1 CARTON	09/19/2023	
4		3 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information			
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
505G(a)(3)	12/01/2007		
	Application Number or Monograph Citation	Application Number or Monograph Marketing Start Citation Date	

## ICY HOT MEDICATED, ADVANCED RELIEF

menthol patch

WATER (UNII: 059QF0KO0R)

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62168-0805
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	210 mg	

Inactive Ingredients			
Ingredient Name	Strength		
MINERAL OIL (UNII: T5L8T28FGP)			
POLYISOBUTYLENE (1000 MW) (UNII: 5XB3A63Y52)			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:62168- 0805-4	300 in 1 BOX	07/05/2021	03/31/2024
1	5 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	505G(a)(3)	12/01/2012	03/31/2024

## Labeler - Lead Chemical Co., Ltd. (693727091)

Revised: 3/2024 Lead Chemical Co., Ltd.