ICY HOT PRO PAIN RELIEF- camphor, menthol patch Lead Chemical Co., Ltd.

ICY HOT® PRO Pain Relief Patch

Active ingredients

Camphor 3% Menthol 5%

Purpose

Topical analgesic

Uses

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

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

When using this product

- 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

- 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

adults and children 12 years of age and older:

- 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 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

aluminum hydroxide, cellulose gum, disodium EDTA, glycerin, methyl acrylate/2ethylhexyl acrylate copolymer, nonoxynol-30, polyacrylic acid, polysorbate 80, propylene glycol, silica, sodium polyacrylate, talc, tartaric acid, titanium dioxide, water

Principal Display Panel - Pouch Label

ICY HOT®

PRO
PAIN RELIEF
PATCH
WEAR FOR UP
TO 8 HOUR
EXTRA STRENGTH WITH 2 PAIN RELIEVERS

MENTHOL 5% CAMPHOR 3%

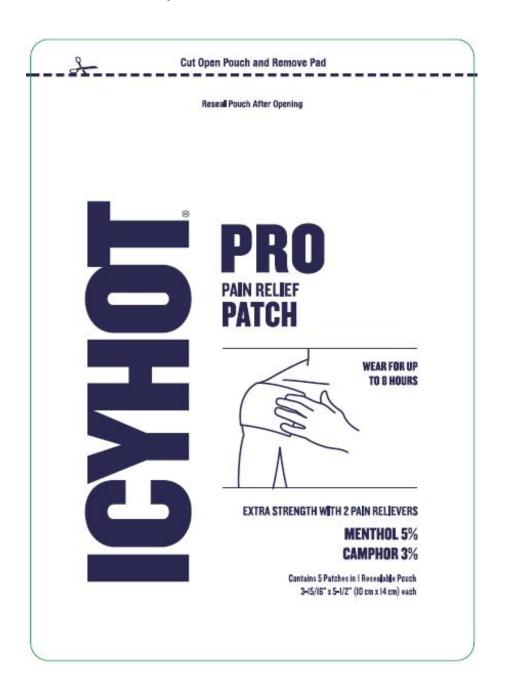
Contains 5 Patches in 1 Resealable Pouch 3-15/16" x 5-1/2" (10 cm x 14 cm) each

SANOFI CONSUMER HEALTH CARE

Dist. by: Chattem, Inc., a Sanofi Company

P.O. Box 2219, Chattanooga, TN 37409-0219 USA

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Label

ICY HOT PRO PAIN RELIEF camphor, menthol patch			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62168-0210
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	,	180 mg		
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	300 mg		

Inactive Ingredients		
Ingredient Name	Strength	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)		
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K6790BS311)		
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)		
GLYCERIN (UNII: PDC6A3C0OX)		
NONOXYNOL-30 (UNII: JJX07DG188)		
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)		
POLYSORBATE 80 (UNII: 60ZP39ZG8H)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)		
TALC (UNII: 7SEV7J4R1U)		
TARTARIC ACID (UNII: W4888I119H)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
WATER (UNII: 059QF0KO0R)		

l	P	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1	NDC:62168- 0210-1	160 in 1 CARTON	01/31/2023		
	1		5 in 1 POUCH; Type 0: Not a Combination Product			

Marketing In	larketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	505G(a)(3)	01/31/2023		

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

Revised: 1/2024 Lead Chemical Co., Ltd.