

RELIEVER- menthol, capsaicin patch

API Solutions, Inc.

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.

API Solutions - Reliever Patch

ACTIVE INGREDIENTS:

MENTHOL 5.00%
CAPSAICIN 0.05%

PURPOSES

TOPICAL ANALGESIC
TOPICAL ANALGESIC

USES:

FOR TEMPORARY RELIEF OF ACHES AND PAINS OF THE MUSCLES AND JOINTS ASSOCIATED WITH ARTHRITIS, SIMPLE BACKACHE, STRAINS, BRUISES AND SPRAINS.

WARNINGS:

FOR EXTERNAL USE ONLY.

WHEN USING THIS PRODUCT

USE ONLY AS DIRECTED

DO NOT USE

DO NOT USE ON, AND AVOID CONTACT WITH, FACE, SCALP, EYES, MOUTH, AND MUCOUS MEMBRANES · DO NOT USE ON WOUNDS OR DAMAGED OR SENSITIVE SKIN · DO NOT USE IN COMBINATION WITH ANY EXTERNAL HEAT SOURCE (HEATING PAD, ETC.) OR FOR 1 HOUR BEFORE OR AFTER BATHING OR SHOWERING · DO NOT USE IN COMBINATION WITH ANY COMPRESSION (BANDAGE, WRAP, BRACE, STOCKING, SOCK, OR SIMILAR DEVICE OR GARMENT) · DO NOT USE IN COMBINATION WITH ANY OTHER EXTERNAL ANALGESIC PRODUCTS.

STOP USE AND ASK A DOCTOR IF

· EXCESSIVE REDNESS, BURNING, SWELLING, IRRITATION, OR DISCOMFORT DEVELOPS IN THE SKIN, EYES, MOUTH OR MUCOUS MEMBRANES · CONDITION WORSENS · PAIN PERSISTS FOR MORE THAN 7 DAYS · SYMPTOMS CLEAR UP AND OCCUR AGAIN WITHIN A FEW DAYS

IF PREGNANT OR BREAST-FEEDING,

ASK A DOCTOR 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 16 YEARS AND OVER: APPLY DIRECTLY TO AFFECTED AREA OF PAIN; CHANGE PATCH 1 TO 2 TIMES DAILY, OR AS DIRECTED BY A DOCTOR ·
CHILDREN UNDER 16 YEARS: ASK A DOCTOR BEFORE USING

HOW TO APPLY:

- CLEAN AND DRY AFFECTED AREA - TEAR OPEN POUCH AND REMOVE ONE PATCH
- REMOVE PROTECTIVE FILM AND APPLY DIRECTLY TO AFFECTED AREA OF PAIN
- RESEAL POUCH CONTAINING UNUSED PATCHES AFTER EACH USE
- WASH HANDS WITH SOAP AND WATER AFTER APPLYING

OTHER INGREDIENTS:

ACRYLIC ACID, ALUMINUM HYDROXIDE, GLYCERIN, METHYL ACRYLATE, CARMELLOSE SODIUM, 2-ETHYLHEXYL ACRYLATE, TARTARIC ACID, POLYACRYLIC ACID, WATER, SODIUM POLYACRYLATE

QUESTIONS

DISTRIBUTED BY:

A.P.I. SOLUTIONS

DAPHNE, AL 36526

FOR QUESTIONS OR COMMENTS PLEASE CALL 855-878-1489

Principal Display Panel

Reliever patch

DRUG FACTS:	
ACTIVE INGREDIENTS:	PURPOSES
Menthol 5.00%	Topical Analgesic
Capsaicin 0.05%	Topical Analgesic

USES:
For temporary relief of minor aches and pains of the muscles and joints associated with arthritis, simple backache, strains, bruises and sprains.

WARNINGS:
For external use only
When using this product • use only as directed • do not use on, and avoid contact with, face, scalp, eyes, mouth, and mucous membranes • do not use on wounds or damaged or sensitive skin • do not use in combination with any external heat source (heating pad, etc.) or for 1 hour before or after bathing or showering • do not use in combination with any compression (bandage, wrap, brace, stocking, sock, or similar device or garment) • do not use in combination with any other external analgesic products.
Stop use and ask a doctor if • excessive redness, burning, swelling, irritation, or discomfort develops in the skin, eyes, mouth or mucous membranes • condition worsens • pain persists for more than 7 days • symptoms clear up and occur again within a few days • If pregnant or breast-feeding, ask a doctor 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 16 years and over: apply directly to affected area of pain; change patch 1 to 2 times daily, or as directed by a doctor • children under 16 years: ask a doctor before using
how to apply:
- clean and dry affected area - tear open pouch and remove one patch
- remove protective film and apply directly to affected area of pain
- reseal pouch containing unused patches after each use
- wash hands with soap and water after applying

OTHER INGREDIENTS:
Acrylic Acid, Aluminum Hydroxide, Glycerin, Methyl Acrylate, Carmellose Sodium, 2-ethylhexylacrylate, Tartaric Acid, Polyacrylic Acid, Polyacrylate, Water, Sodium Polyacrylate

Distributed by:
A.P.I. SOLUTIONS
Daphne, AL 36526
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46144-163-01



RELIEVER PATCH

TOPICAL ANALGESIC - MENTHOL 5%, CAPSAICIN 0.05%

Qty: 15 Patches: (5 per Resealable Pouch) × 3

LOT:

EXP:

NDC: 46144-163-01

RELIEVER

menthol, capsaicin patch

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:46 144-163

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5 g in 100 g
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.05 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ACRYLIC ACID (UNII: J94PBK7X8S)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYL ACRYLATE (UNII: WC487PR91H)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
2-ETHYLHEXYL ACRYLATE (UNII: HR49R9S6XG)	
TARTARIC ACID (UNII: W4888I119H)	
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	
WATER (UNII: 059QF0KO0R)	
SODIUM POLYACRYLATE (250000 MW) (UNII: 05115JN12J)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46144-163-01	3 in 1 BOX	10/01/2015	
1		5 in 1 POUCH		
1		100 g in 1 PATCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/01/2015	

Labeler - API Solutions, Inc. (831870824)

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API Solutions, Inc.