

PAIN RELIEF HOT PATCH- menthol and capsaicin patch
Universal Distribution Center LLC

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.

PAIN RELIEF HOT PATCH

Drug Facts

Active Ingredients (in each gram)

Menthol 30 mg

Capsaicin 0.83 mg

Purpose

Topical Analgesic

Uses

Temporarily relieves minor pain associated with:

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

WARNINGS:

EXTERNAL USE ONLY

When using this product • use only as directed • do not bandage tightly or use with a heating pad • avoid contact with eyes and mucous membranes • do not apply to wounds or damaged skin.

STOP USE and ask a doctor if • condition worsens • symptoms persist for more than 7 days or clear up and occur again within a few days • redness is present • skin irritation develops

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 (1-800-222-1222) immediately.

DIRECTIONS

Adults and Children 12 years of age and older:

- Partially peel back protective film and apply exposed patch to site of pain. Carefully remove remaining film while pressing patch to skin for secure adhesions
- Apply to affected area not more than 3 to 4 times a daily

Children under 12 years of age: DO NOT use without consulting a doctor.

Other information

- store at room temperature 68° to 77°F (20 to 25°C)

Inactive ingredients

glycerin, sodium polyacrylate, aluminum glycinate, kaolin, methylparaben, propylparaben, alcohol, titanium dioxide, tartaric acid, sorbitan monooleate, polysorbate 80, purified water

EXTRA STRENGTH PAIN RELIEF HOT PATCH soothes and relieves pain associated with minor aches and pains. It is ideal for small areas such as arm, neck and leg.

FAST-ACTING PAIN RELIEF

Distributed by:

Universal Distribution Center

96 Distribution Boulevard • Edison, NJ 08817

Packaging

✂ Cut open pouch



EXTRA STRENGTH PAIN RELIEF
HOT PATCH

For fast relief of minor aches and pains due to:

- Arthritis
- Strains
- Bruises
- Sprains

2 Patches
3.15 in x 4.72 in
(8 cm x 12 cm)

✂ Cut open pouch



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HOT PATCH

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 **LOT:**
EXP:

ITEM#82634
6 76979 82634 9
Made in P.R.C.

PAIN RELIEF HOT PATCH

menthol and capsaicin patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52000-046
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	30 mg in 1 g
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.83 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM POLYACRYLATE (250000 MW) (UNII: 05H5JN2J)	
DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS (UNII: 1K713C615K)	
KAOLIN (UNII: 24H4NWX5CO)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
ALCOHOL (UNII: 3K9958V90M)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TARTARIC ACID (UNII: W4888I119H)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52000-046-42	1 in 1 BOX	03/23/2020	
1		2 in 1 POUCH		
1		0.206 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	03/23/2020	

Labeler - Universal Distribution Center LLC (019180459)

Registrant - Universal Distribution Center LLC (019180459)

Establishment

Name	Address	ID/FEI	Business Operations
Zhejiang Dingtai Pharmaceutical Co., Ltd		420598724	manufacture(52000-046)

