

AMERIPATCH- menthol and capsaicin patch
Meds Direct Rx, 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.

AmeriPatch (69418-003)

ACTIVE INGREDIENTS:

Menthol 5.00%
Capsaicin 0.0375%

Analgesic/Counterirritant
External Analgesic

USES:

Use for the temporary relief of minor aches and muscle pains associated with arthritis, simple backache, strains, muscle soreness and stiffness.

WARNINGS:

- For external use only. Use only as directed. Avoid contact with eyes and mucous membranes.
- Do not cover with bandage.
- Do not use on wounds or damaged skin.
- Do not use if you are allergic to Menthol.
- Stop use and ask a doctor if conditions worsen, symptoms persist for more than 7 days or clear up and occur again within a few days.
- or a rash, itching or excessive skin irritation occurs.

Keep out of reach of children.

Consult Physician for children under 12.

DIRECTIONS:

- Adults and children 12 years and over apply to affected area; change patch 1 to 2 times daily.
- Children under 12 years, consult physician before use
- How to apply:

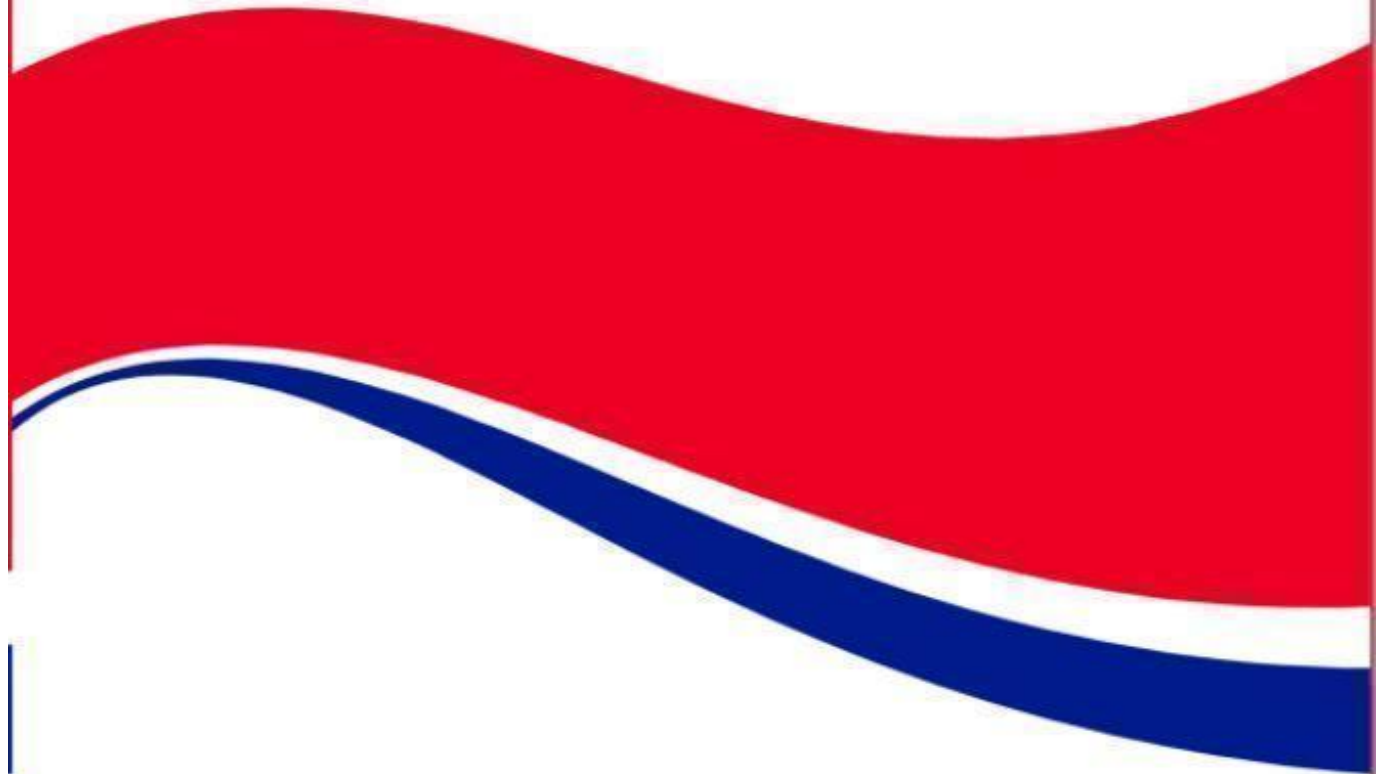
Clean and dry affected area
Cut open pouch and remove patch
Remove protective film and apply directly to area of pain
Apply to affected area not more than 3 times daily
Wash hands with soap after applying patch
Reseal pouch containing unused patches

OTHER INGREDIENTS:

Water, Glycerine, Sodium Polyacrylate, Polysorbate 80, Aloe Barbadesis Leaf (Aloe Vera Gel) Juice, EDTA Disodium salt, Diaxolidinyl Urea, Methylparaben, Iodopronyl Butylcarbamate, Propylparaben.

Package Label - AmeriPatch (69418-003-15)

Ameri☆Patch



NDC: 69418-003-15

Ameri☆Patch

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DRUG FACTS:

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Store below 25° degrees
Avoid direct sunlight.

Manufactured For: **Meds Direct Rx, Inc**
882 Third Avenue 10th Floor Suite 1000
Brooklyn, NY 11232
Questions or Comments call 855-480-MEDS

Made in China

AMERIPATCH

menthol and capsaicin patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69418-003
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	0.0375 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

SODIUM POLYACRYLATE (250000 MW) (UNII: 05115JN12J)	
PROPYLPARABEN (UNII: Z8IX2SC10H)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69418-003-15	3 in 1 BOX		
1		5 in 1 POUCH		
1		15 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	01/31/2015	

Labeler - Meds Direct Rx, Inc. (064053428)

Establishment			
Name	Address	ID/FEI	Business Operations
Foshan Aqua Gel Biotech Co. Ltd		529128763	manufacture(69418-003)