PATCH- menthol and caps aicin patch Meds Direct Rx of NY 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.



DRUG FACTS: NDC: 69418-001-01

ACTIVE INGREDIENTS:

Menthol 5.00% Analgesic / Counterirritant

Capsaicin 0.0375% External Analgestic

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.
- Keep out of reach of children. Consult Physician for children under 12.
- 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.

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:

Store below 25° degrees

vvater, Giycerine, Sodium Foiyacrylate, Foiyscorbate ou, Aloe Barbadesis Leaf (Aloe Vera Gel) Juice, EDTA Disodium salt, Diazolidinyl Urea, Methylparaben, Iodoproynyl Butylcabamate, Propylparaben.

Avoid direct sunlight.

Manufactured For: MEDS DIRECT RX of NY LLC

882 Third Avenue 10th Floor Suite 1000

Brooklyn, NY 11232

Questions or Comments call 855-480-MEDS

Made in China



Ameri☆Patch

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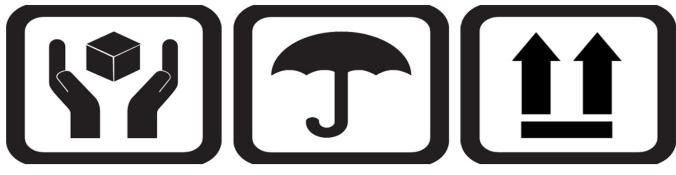
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PATCH

menthol and capsaicin patch

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:69418-000

Route	οf	Δd	min	ictra	ation
ROME	01	AU		ISIT	111011

TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
menthol (UNII: L7T10EIP3A) (menthol - UNII:L7T10EIP3A)	menthol	5 g in 100 g	

Inactive Ingredients			
Ingredient Name	Strength		
water (UNII: 059QF0KO0R)			
glycerin (UNII: PDC6A3C0OX)			
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)			
POLYSORBATE 80 (UNII: 6OZP39ZG8H)			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)			
diazolidinyl urea (UNII: H5RIZ3MPW4)			
methylparaben (UNII: A2I8 C7HI9 T)			
iodopropynyl butylcarbamate (UNII: 603P14DHEB)			
PROPYLPARABEN (UNII: Z8IX2SC1OH)			

Product Characteristics				
Color		Score		
Shape	RECTANGLE (rectangular patch)	Size		
Flavor		Imprint Code		
Contains				

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
NDC:69418- 000-00	100 g in 1 POUCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)	12/0 1/20 14	



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Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	12/0 1/20 14		

Labeler - Meds Direct Rx of NY LLC (190337654)

Revised: 1/2015 Meds Direct Rx of NY LLC