MENDEX- menthol, capsaicin patch Patchwerx Labs, 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.

MENDEX PATCH

ACTIVE INGREDIENTS

Menthol 5.00%

Capsaicin 0.0375%

PURPOSE

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.
- 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 rash, itching or excessive skin irritation occurs.

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children

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

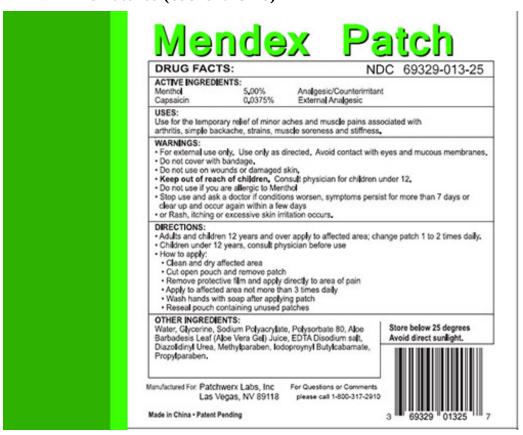
Remove protective film and apply directly to area of pain

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 Barbadensis Leaf (Aloe Vera Gel) Juice, EDTA Disodiumm Salt, Diazolidinyl Urea, Methylparaben, Iodoproynyl Butylcabamate, Propylparaben.

MENDEX 25 Patches (69329-013-25)



CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)

MENDEX menthol, capsaicin patch **Product Information** Product Type HUMAN OTC DRUG Item Code (Source) NDC:69329-013 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

.0375 g in 100 g

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
GLYCERIN (UNII: PDC6A3C0OX)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)				
EDETATE DISO DIUM (UNII: 7FLD9 1C8 6 K)				
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)				
METHYLPARABEN (UNII: A2I8 C7HI9 T)				
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				

F	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:69329-013-25	25 in 1 BOX				
1		10 g in 1 PATCH				

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not final	part348	11/10/2014				

Labeler - Patchwerx Labs, Inc (079584480)

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