

MEDROX- menthol, capsaicin patch
Aidarex Pharmaceuticals 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.

MEDROX 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

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 Barbadosis Leaf (Aloe Vera Gel) Juice, EDTA Disodium Salt, Diazolidinyl Urea, Methylparaben, Iodopropynyl Butylcabamate, Propylparaben.

MEDROX Patch 5 Patches (33261-0884-01)

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT, KEEP OUT OF REACH OF CHILDREN. STORE AT CONTROLLED ROOM TEMP. 15-30°C (59-86°F)

Packaged and Distributed by: **AIDAREX PHARMACEUTICALS LLC.**

MEDROX PATCH

5% / 0.0375%

CONTAINS THE FOLLOWING ACTIVE INGREDIENTS:

MENTHOL.....5%

CAPSAICIN.....0.0375%

5 / BOX

MEDROX PATCH 5 / BOX
5% / 0.0375%

NDC: 33261-0884-01
RX QLS0000

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RX QLS0000

APPLY _____ TIMES DAILY

APLIQUE _____ VECES AL DIA

MFG: FOR: PHARMACEUTICA NORTH AMERICA, GLENDALE, CA 91204

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RX QLS0000

PATIENT LABEL

LOG

CHART

BILL LABEL

MEDROX

menthol, capsaicin patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:33261-884(NDC:45861-014)
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)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:33261-884-01	5 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	06/13/2012	

Labeler - Aidarex Pharmaceuticals LLC (801503249)

Revised: 1/2014

Aidarex Pharmaceuticals LLC