

## **MEDROX - menthol, capsaicin patch**

### **Unit Dose Services**

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

## MEDROX (MENTHOL, CAPSAICIN ) PATCH

NDC: 50436-9991-1  
**MEDROX PATCH**  
**(MENTHOL 5.00%)**  
**(CAPSAICIN 0.0375%)**

**5 PATCHES**

**WARNING:**  
 KEEP OUT OF REACH OF CHILDREN.  
 STORE BELOW 25 DEGREES.  
 AVOID DIRECT SUNLIGHT.

MFG FOR: PHARMACEUTICA NORTH  
 AMERICA GLENDALE, CA 91204

MFG NDC: 45861-0014-05  
 MFG LOT: XXXXXXXX  
 LOT: XXXX      EXP: XXXXX  
 Pkg by: Unit Dose Services, LLC Miami, FL 33179



NDC: 50436-9991-1    5 PATCHES  
 DRUG: MEDROX PATCH    (CAPSAICIN 0.0375%)  
 (MENTHOL 5.00%)  
 LOT: XXXX      EXP: XXXXX

NDC: 50436-9991-1    5 PATCHES  
 DRUG: MEDROX PATCH    (CAPSAICIN 0.0375%)  
 (MENTHOL 5.00%)  
 LOT: XXXX      EXP: XXXXX

NDC: 50436-9991-1    5 PATCHES  
 DRUG: MEDROX PATCH    (CAPSAICIN 0.0375%)  
 (MENTHOL 5.00%)  
 LOT: XXXX      EXP: XXXXX

NDC: 50436-9991-1    5 PATCHES  
 DRUG: MEDROX PATCH    (CAPSAICIN 0.0375%)  
 (MENTHOL 5.00%)  
 LOT: XXXX      EXP: XXXXX

## MEDROX

menthol, capsaicin patch

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50436-9991(NDC:45861-014)
<b>Route of Administration</b>	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)

**METHYL PARABEN** (UNII: A2I8C7HI9T)

**IODOPROPYNYL BUTYLCARBAMATE** (UNII: 603P14DHEB)

**PROPYL PARABEN** (UNII: Z8IX2SC1OH)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50436-9991-1	5 g in 1 BOX		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/13/2012	

**Labeler** - Unit Dose Services (831995316)

**Registrant** - Unit Dose Services (831995316)

### Establishment

Name	Address	ID/FEI	Business Operations
Unit Dose Services		831995316	REPACK(50436-9991)

Revised: 6/2012

Unit Dose Services