MEDROX- menthol, capsaicin patch
Preferred Pharmaceuticals, 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.

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

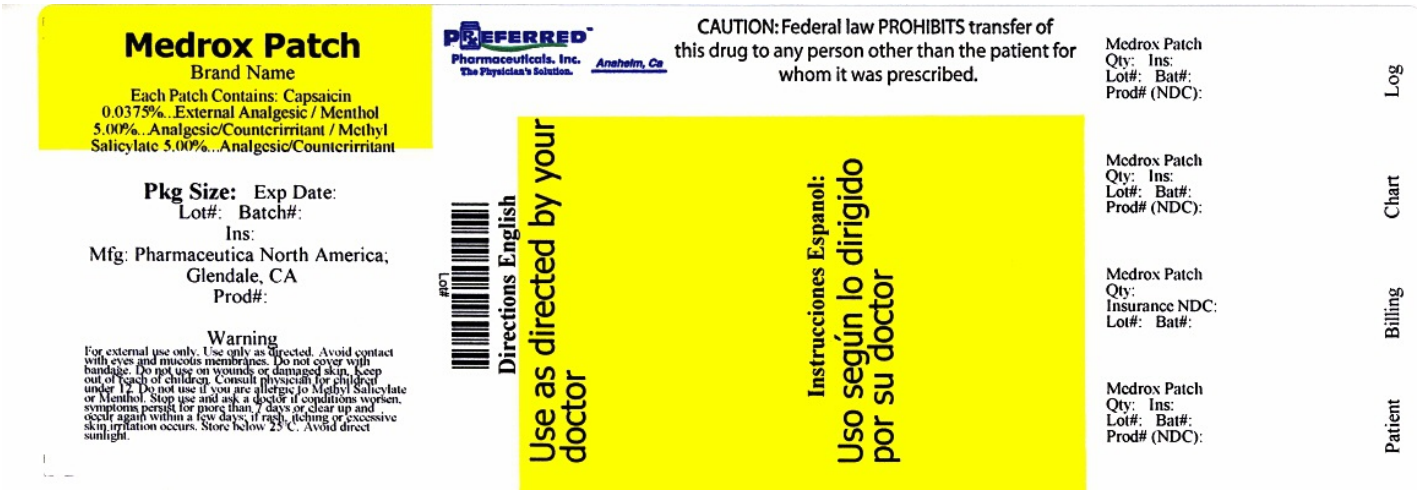
HOW SUPPLIED

5 Patches – 68788-6755-5

30 Patches – 68788-6755-3

Relabeled by Preferred Pharmaceuticals, Inc.

MEDROX Patch



MEDROX

menthol, capsaicin patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68788-6755(NDC:45861-014)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	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:68788-6755-5	5 in 1 BOX	07/27/2012	
1		10 g in 1 PATCH; Type 0: Not a Combination Product		
2	NDC:68788-6755-3	30 in 1 BAG	07/27/2012	
2		10 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	07/27/2012	

Labeler - Preferred Pharmaceuticals, Inc. (791119022)

Registrant - Preferred Pharmaceuticals, Inc. (791119022)

Establishment

Name	Address	ID/FEI	Business Operations
Preferred Pharmaceuticals, Inc.		791119022	RELABEL(68788-6755)

Revised: 12/2017 Preferred Pharmaceuticals, Inc.