MEDROX- menthol, capsaicin, methyl salicylate patch
Pharmaceutica North America, 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 5%

methyl salicylate 5% analgesic/counterirritant

menthol 5% analgesic/counterirritant

capsaicin 0.0375% external analgesic

water, glycerine, sodium polyacrylate, polysorbate 80, alo barbadesis leaf (aloe vera gel) juice, EDTA disodium salt, diazolidinyl urea, methylparaben, idopropynl butylcabamate, propylparaben.

Keep out of reach of children. consult physician for children under 12.

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 are not move than 3 times daily
- wash hands with soap after applying patch
- reseal pouch containing unused patches

use for the temporary relief of minor aches and muscle pains associated with arthritis, simple backache, strains, muscle soreness and stiffness.

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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 methyl salicylate or 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.

if rash, itching or excessive skin irritations occurs.

store below 25 degrees, avoid direct sunlight.

MEDROX

menthol, capsaicin, methyl salicylate patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:45861-009
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	.0375 g in 100 g
methyl salicylate (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	methyl salicylate	5 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
water (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
DISODIUM SULFOSALICYLATE (UNII: WFP6MAA96R)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:45861-009-06	10 g in 1 PACKET		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/27/2011	

Labeler - Pharmaceutica North America, Inc. (962739699)

Registrant - SMARTDATA SUZHOU CO., Ltd (529507479)

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