MEDROX - methyl salicylate, menthol, capsaicin ointment
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 (Medroxin)

DRUG FACTS:

ACTIVE INGREDIENTS

Methyl Salicylate	20.00%
Menthol	5.00%
Capsaicin	0.0375%

PURPOSE

Analgesic/Counterirritant

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.

KEEP OUT OF REACH OF CHILDREN

Consult physician for children under 12.

DIRECTIONS

Apply product directly to affected area. Product may be used as necessary, but should not be used more than four times per day.

OTHER INGREDIENTS

Deionized Water, Cetyl Alcohol, PEG-150 Distearate, Isopropyl Myristate, Glycerin, Sodium Lauryl Sulfate, Polysorbate-20, Triethanolamine, Acrylates Copolymer, Propylene Glycol, Methyl Paraben, Propyl Paraben, Diazolidinyl Urea, FD and C Blue 1, D and C Yellow 5

MEDROX (METHYL SALICYLATE, MENTHOL, CAPSAICIN) OINTMENT

MEDROX

methyl salicylate, menthol, capsaicin ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50436-9994(NDC:45861-001)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	20 g in 100 g
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)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
TROLAMINE (UNII: 9O3K93S3TK)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50436-9994-1	120 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	02/09/2011	

Labeler - Unit Dose Services (831995316)

Registrant - Unit Dose Services (831995316)

Establishment

Name	Address	ID/FEI	Business Operations
Unit Dose Services		831995316	REPACK(50436-9994)

Revised: 2/2011 Unit Dose Services