MEDROX-RX - methyl salicylate, menthol, capsaicin ointment
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-Rx

methyl salicylate 20.00 % topical analgesic

menthol 7.00 % topical analgesic

capsaicin 0.050 % external analgesic

acrylates copolymer, aloe barbadensis leaf (aloe vera gel) juice, aqua (deionized water), cetyl alcohol, ethylhexylglycerin, glycerin, isopropyl myristate, peg-150 disterate, phenoxyethanol, polysorbate-20, sodium lauryl sulfate, triethanolamine

keep out of reach of children. if swallowed, consult physician.

apply directly to affected area. do not use more than four times per day.

for temporary relief of minor aches and pains of the muscles and joints associated with simple arthritis, sprains, bruises and simple backache.

for temporary relief of minor aches and pains of the muscles and joints associated with simple arthritis, sprains, bruises and simple backache.

for external use only

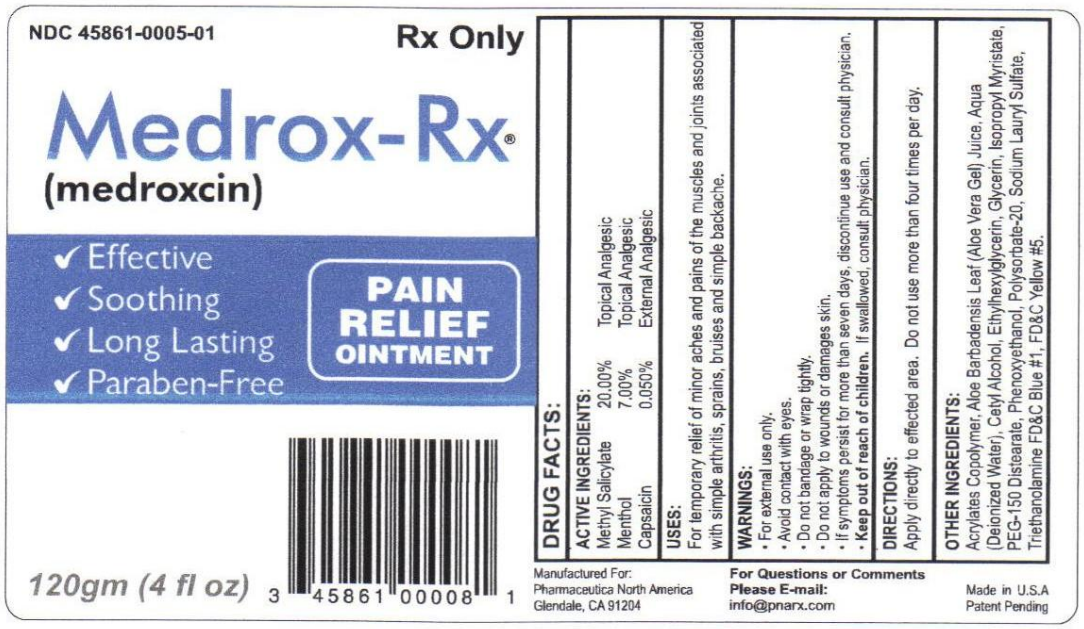
avoid contact with eyes

do not bandage or wrap tightly

do not apply to wounds or damages skin

if symptoms persist for more than seven days, discontinue use and consult physician

keep out of reach of children. if swallowed consult physician.



Rx Only

Medrox-Rx

(medroxcin) Pain relief ointment

effecive, soothing, long lasting, paraben-free

MEDROX-RX

methyl salicylate, menthol, capsaicin ointment

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:45861-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
methyl salicylate (UNII: LAV5U5022Y) (methyl salicylate - UNII:LAV5U5022Y)	methyl salicylate	24 g in 120 g
menthol (UNII: L7T10EIP3A) (menthol - UNII:L7T10EIP3A)	menthol	8.4 g in 120 g
capsaicin (UNII: S07O44R1ZM) (capsaicin - UNII:S07O44R1ZM)	capsaicin	0.6 g in 120 g

Inactive Ingredients	
Ingredient Name	**Strength**
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

WATER (UNII: 059QF0KO0R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TROLAMINE (UNII: 9O3K93S3TK)	
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:45861-005-01	120 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part348	10/27/2011	

Labeler - Pharmaceutica North America, Inc. (962739699)

Registrant - Pharmaceutica North America, Inc. (962739699)

Establishment

Name	Address	ID/FEI	Business Operations
Pure Source		969241041	manufacture

Revised: 10/2011 Pharmaceutica North America, Inc.