

MEDROX- methyl salicylate, menthol, capsaicin ointment
Dispensing Solutions, 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 (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

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 68258-3984-04

BULK SOURCE DATA
MFD. FOR: PHARMACEUTICA NORTH AMERICA
GLENDALE, CA 91204
PRODUCT ID:
WHITE ROUND BOTTLE WHITE /
BLACK / NAVY BLUE LABEL
PRINTED NDC 45861-0001-01
BULK SOURCE NDC: 45861-0001-01
MFR. LOT: XXXXXX
PEDIGREE #: 5335346
DISPENSE IN THIS
TIGHT/LIGHT RESISTANT CONTAINER

**APPLY TOPICALLY
TO AFFECTED AREA(S)
TIMES A DAY AS
DIRECTED. DO NOT USE
MORE THAN 4 TIMES PER
DAY. SEE WARNINGS.
FOR EXTERNAL USE ONLY.**

DispenseQuick™
Making Medicine Easy

MEDROX
120 gm OINTMENT
NDC 68258-3984-04
PRODUCT # 3M0604

Rev. Date: 01/13

ACTIVE INGREDIENTS:
METHYL SALICYLATE 20.00%
MENTHOL 5.00%
CAPSAICIN 0.0375%
(PURPOSES: ANALGESIC/COUNTERIRRITANT/
EXTERNAL ANALGESIC)
FD&C YELLOW No.5

LOT# SAMPLE EXP: 00-00 Rx # 3077565

**WARNING: KEEP OUT OF
CHILDREN'S REACH
STORE AT ROOM TEMPERATURE. SEE USP.**

3M0604 NDC 68258-3984-04
MEDROX
120 gm OINTMENT
LOT # SAMPLE EXP: 00-00
MN 45861-0001-01 RX# 3077565

3M0604 NDC 68258-3984-04
MEDROX
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3M0604 NDC 68258-3984-04
MEDROX
120 gm OINTMENT
LOT # SAMPLE EXP: 00-00
MN 45861-0001-01 RX# 3077565

Packaged Exclusively By:
DISPENSING SOLUTIONS^{INC}
Santa Ana, CA 92704

MEDROX

methyl salicylate, menthol, capsaicin ointment

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|-------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:68258-3984(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: 059QF0K00R) | |
| 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) | |

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| Packaging | | | | |
|------------------|------------------|---------------------|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:68258-3984-4 | 120 g in 1 BOTTLE | | |

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

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Labeler - Dispensing Solutions, Inc. (066070785)

Registrant - PSS World Medical, Inc. (101822682)

| Establishment | | | | |
|----------------------------|---------|-----------|--|--|
| Name | Address | ID/FEI | Business Operations | |
| Dispensing Solutions, Inc. | | 066070785 | relabel(68258-3984) , repack(68258-3984) | |