

**MEDROX- menthol, capsaicin patch**  
**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.*

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**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 Barbadosensis Leaf (Aloe Vera Gel) Juice, EDTA Disodium Salt, Diazolidinyl Urea, Methylparaben, Iodopropynyl Butylcabamate, Propylparaben.

## MEDROX Patch 5 Patches

<p><b>BULK SOURCE DATA</b> MFD. FOR: PHARMACEUTICA NORTH AMERICA GLENDALE, CA 91204</p> <p><b>PRODUCT ID:</b> NAVY BLUE / BLUE / WHITE / BLACK BOX PRINTED NDC 45861-0014-05</p> <p><b>BULK SOURCE NDC: 45861-0014-05</b> MFR. LOT: XXXXXX PEDIGREE #: 5396894 DISPENSE IN THIS TIGHT/LIGHT RESISTANT CONTAINER</p>  <p><b>APPLY ONE PATCH TOPICALLY ___ TIME(S) A DAY TO AFFECTED AREA AS DIRECTED. SEE WARNINGS AND DIRECTIONS FOR USE. AVOID DIRECT SUNLIGHT.</b></p>	 <p><b>MEDROX</b> <b>5 PATCHES</b> <b>NDC 68258-2993-05</b> <b>PRODUCT # 2M0205</b></p> <p><b>ACTIVE INGREDIENTS</b> MENTHOL . . . . 5.00% (PURPOSE: ANALGESIC/COUNTERIRRITANT) CAPSAICIN . . . . 0.0375% (PURPOSE: EXTERNAL ANALGESIC)</p> <p>LOT# SAMPLE EXP: 00-00 Rx # 29969034</p>	<p><b>WARNING: KEEP OUT OF CHILDREN'S REACH</b> <b>STORE BELOW 77° F. SEE USP.</b></p> <p>2M0205 NDC 68258-2993-05 MEDROX 5 PATCHES LOT # SAMPLE EXP: 00-00 MN 45861-0014-05 RX# 29969034</p> <p>2M0205 NDC 68258-2993-05 MEDROX 5 PATCHES LOT # SAMPLE EXP: 00-00 MN 45861-0014-05 RX# 29969034</p> <p>2M0205 NDC 68258-2993-05 MEDROX 5 PATCHES LOT # SAMPLE EXP: 00-00 MN 45861-0014-05 RX# 29969034</p>  <p>Packaged Exclusively By: <b>DISPENSING SOLUTIONS<sup>Phc</sup></b> Santa Ana, CA 92704</p>
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## MEDROX

menthol, capsaicin patch

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68258-2993(NDC:45861-014)
<b>Route of Administration</b>	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	0.0375 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	

<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>DIAZOLIDINYL UREA</b> (UNII: H5RIZ3MPW4)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>IODOPROPYNYL BUTYLCARBAMATE</b> (UNII: 603P14DHEB)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	

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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68258-2993-5	5 in 1 BOX		
1		10 g in 1 PATCH		

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### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/13/2012	

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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(68258-2993) , repack(68258-2993)

Revised: 10/2013

Dispensing Solutions, Inc.