

**NEW TEROGIN- methyl salicylate, capsaicin, and menthol lotion**  
**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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**New Terocin Topical Pain Relief Lotion**

**Active ingredient**

Methyl Salicylate 25%

Capsaicin 0.025%

Menthol 10%

**Purpose**

Topical Analgesic

**Uses**

Temporarily relieves mild aches and pains of muscles or joints.

**Warnings**

- Only for external use.
- **Do not use:** on open wounds, cuts, damaged or infected skin as well as in the eyes, mouth, genitals, or any other mucous membranes.
- **Consult your physician:** if pain is persistent or worsens or if using any other topical pain products.
- Call poison control if swallowed. If contact with the eyes occurs, rinse eyes thoroughly with cold water.

**Keep out of reach of children.**

Consult physician for children under 12.

**Directions**

Wash and dry affected area. Shake bottle well before each use and gently rub over area of pain. Use is not recommended more than four times a day. Wash hands immediately afterwards to avoid contact with eyes.

**Inactive ingredients**

Water (Aqua), Cetyl Alcohol, Stearic Acid, Glyceryl Stearate, PEG-100 Stearate, Propylene Glycol, Dimethyl Sulfone, Lavandula Angustifolia (Lavendar) Oil, Lidocaine, Aloe Barbadosensis Leaf Extract, Borago Officinalis Seed Oil, Boswellia Serrata Extract, Xanthan Gum, Triethanolamine, Methylparaben, Propylparaben, DMDM Hydantoin, Iodopropynyl Butylcarbamate.

## Package/Label Principal Display Panel

NDC 68258-3981-04

NDC 50488-1129-1

New Terocin

Topical Pain

Relief Lotion

Long Lasting

Soothing Effect

120 ml (4 fl oz.)

Manufactured for: Alexso Inc.

Thousand Oaks, CA 91360

Made in U.S.A.

Patent Pending

Store in a dry, cool place

For Comments or Questions,

call 888-495-6075

### Bottle Label

The image shows a detailed view of the bottle label for Terocin Lotion. The label is divided into several sections. On the left, there is a 'BULK SOURCE DATA' section with manufacturer information (ALEXSO INC., THOUSAND OAKS, CA 91360), a 'PRODUCT ID' section with a barcode, and an 'APPLY TOPICALLY TO AFFECTED AREA(S)' section with usage instructions. The center features the 'DispenseQuick' logo with the tagline 'Making Medicine Easy', the product name 'TEROCIN', the volume '4 fl oz LOTION', and the NDC and product numbers. Below this, it lists the 'ACTIVE INGREDIENTS: METHYL SALICYLATE . . . 25%, CAPSAICIN . . . 0.025%, MENTHOL . . . 10 %' and the purpose '(PURPOSE: TOPICAL ANALGESIC)'. A 'LOT# SAMPLE EXP: 00-00 Rx # 32446050' is printed at the bottom. On the right, there is a 'WARNING: KEEP OUT OF CHILDREN'S REACH STORE IN A DRY, COOL PLACE' and three identical '3T2104 NDC 68258-3981-04 TEROCIN 4 fl oz LOTION LOT # SAMPLE EXP: 00-00 MN 50488-1129-01 RX# 32446050' labels. At the bottom right, it says 'Packaged Exclusively By: DISPENSING SOLUTIONS inc Santa Ana, CA 92704' with a logo.

### Bottle Label

## NEW TEROCIN

methyl salicylate, capsaicin, and menthol lotion

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68258-3981(NDC:50488-1129)
Route of Administration	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	25 g in 100 mL
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.025 g in 100 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 g in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
LIDOCAINE (UNII: 98PI200987)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BORAGE OIL (UNII: F8XAG1755S)	
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)	
XANTHAN GUM (UNII: TTV12P4NEE)	
TROLAMINE (UNII: 9O3K93S3TK)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
IODOPROPYNYL BUTYL CARBAMATE (UNII: 603P14DHEB)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68258-3981-4	120 mL in 1 BOTTLE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/13/2013	

**Labeler** - Dispensing Solutions, Inc. (066070785)

**Registrant** - PSS World Medical, Inc. (101822682)

## Establishment

Name	Address	ID/FEI	Business Operations
Dispensing Solutions, Inc.		066070785	relabel(68258-3981) , repack(68258-3981)

