

## **NEW TEROCIN- methyl salicylate, capsaicin, and menthol lotion**

### **A-S Medication Solutions**

*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**

### **Active ingredients:**

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.

### **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:**

Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Borago Officinalis (Borage) Seed Oil, Boswellia Serrata Extract, C12-15 Alkyl Benzoate, Cetearyl Alcohol, Cetyl Alcohol, Diazolidinyl Urea, Dimethyl Sulfone (DMSO), DMDM Hydantoin, Glyceryl Stearate, Lavandula Angustifolia (Lavender) Oil, Methyl Paraben, PEG-100 Stearate, Polysorbate-20, Polysorbate-60, Propyl Paraben, Propylene Glycol, Stearic Acid, Stearyl Alcohol, Triethanolamine, Xanthan Gum.

## HOW SUPPLIED

Product: 50090-1353

NDC: 50090-1353-0 120 mL in a BOTTLE

## Methyl Salicylate, Capsaicin, and Menthol



## NEW TEROGIN

methyl salicylate, capsaicin, and menthol lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50090-1353(NDC:50488-1129)
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>DIAZOLIDINYL UREA</b> (UNII: H5RIZ3MPW4)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)	
<b>DIMETHYL SULFONE</b> (UNII: 9H4PO4Z4FT)	
<b>LAVENDER OIL</b> (UNII: ZBP1YXW0H8)	
<b>BORAGE SEED OIL</b> (UNII: F8XAG1755S)	
<b>INDIAN FRANKINCENSE</b> (UNII: 4PW41QCO2M)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>DMDM HYDANTOIN</b> (UNII: BYR0546TOW)	
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-1353-0	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/28/2014	

## Marketing Information

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

**Labeler** - A-S Medication Solutions (830016429)

## Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-1353)