

## **TEROCIN- methyl salicylate, capsaicin, and menthol lotion** **medsource pharmaceuticals**

*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 Teroцин 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.

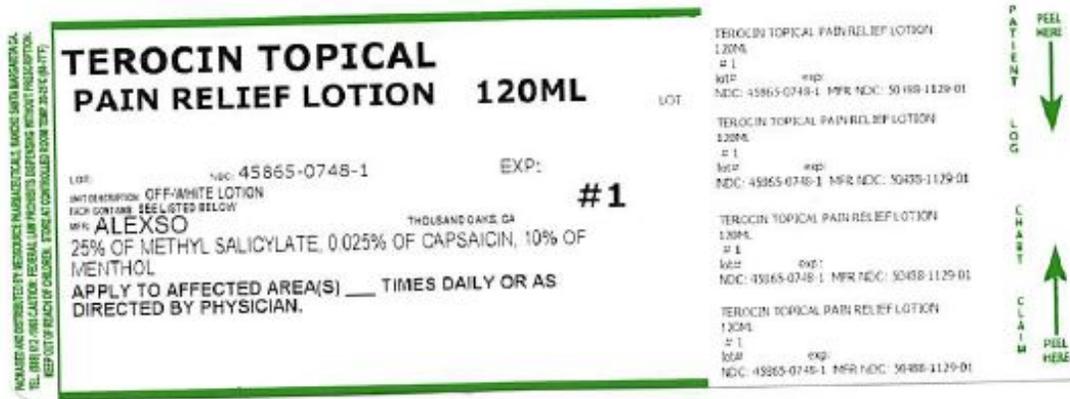
#### **Directions**

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



## TEROCIN

methyl salicylate, capsaicin, and menthol lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:45865-748(NDC:50488-1129)
<b>Route of Administration</b>	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 BUTYLCARBAMATE (UNII: 603P14DHEB)**

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45865-748-01	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2018	

### Marketing Information

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

**Labeler** - medsource pharmaceuticals (833685915)

### Establishment

Name	Address	ID/FEI	Business Operations
medsource pharmaceuticals		833685915	repack(45865-748)

Revised: 12/2018

medsource pharmaceuticals