

**NEW TEROGIN- methyl salicylate, capsaicin, and menthol lotion**  
**Advanced Rx Pharmacy of Tennessee, LLC**

*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 Lotion**

Methyl Salicylate 25%  
Capsaicin 0.025%  
Menthol 10%

Topical Analgesic

**Uses**

Temporarily relieves mild aches and pains of muscles or joints.

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.

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**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.

As directed

Consult your physician

Aloe Barbadosensis 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.

Bottle of:

120ml NDC: 80425-0256-01

Packed By:  
**AdvancedRx**  
Nashville TN, 37217



Store at 20°-25°C (68°-77°F)  
Caution: Federal law PROHIBITS Transfer of this drug to any person other than the patient for whom it was prescribed.

**NEW TEROGIN LOTION**

**120 ML**

NDC: 80425-0256-01 Source NDC: 50488-1129-01  
Lot: XXXXXXXX Expires: 3/31/2024



NEW TEROGIN LOTION 120 ML  
NDC: 80425-0256-01  
Source NDC: 50488-1129-01  
Lot: XXXXXXXX Expi:3/31/2024

ALEXSO INC  
S/N: 000000149670

## NEW TEROGIN

methyl salicylate, capsaicin, and menthol lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:80425-0256(NDC:50488-1129)
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 g in 100 mL
<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

### Inactive Ingredients

Ingredient Name	Strength
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)	
<b>INDIAN FRANKINCENSE</b> (UNII: 4PW41QCO2M)	
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>DIAZOLIDINYL UREA</b> (UNII: H5RIZ3MPW4)	
<b>WATER</b> (UNII: 059QF0KOOR)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)	
<b>LAVENDER OIL</b> (UNII: ZBP1YXW0H8)	
<b>BORAGE SEED OIL</b> (UNII: F8XAG1755S)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	

<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>DIMETHYL SULFONE</b> (UNII: 9H4PO4Z4FT)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>DMDM HYDANTOIN</b> (UNII: BYR0546TOW)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80425-0256-1	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/15/2023	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	02/15/2023	

**Labeler** - Advanced Rx Pharmacy of Tennessee, LLC (117023142)

### Establishment

Name	Address	ID/FEI	Business Operations
Advanced Rx Pharmacy of Tennessee, LLC		117023142	repack(80425-0256)

Revised: 2/2023

Advanced Rx Pharmacy of Tennessee, LLC