

NEW TEROGIN- methyl salicylate, capsaicin, and menthol lotion

A-S Medication Solutions

NEW TEROGIN

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			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50090-1353(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		
ALOE BARBADENSIS LEAF JUICE (UNII: ZY81Z83H0X)			

WATER (UNII: 059QF0KO0R)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
CETYL ALCOHOL (UNII: 936JST6JCN)
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)
STEARIC ACID (UNII: 4ELV7Z65AP)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
PEG-100 MONOSTEARATE (UNII: YD01N1999R)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
POLYSORBATE 60 (UNII: CAL22UVI4M)
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)
LAVANDULA ANGUSTIFOLIA (LAVENDER) OIL (UNII: ZBP1YXW0H8)
BORAGE OIL (UNII: F8XAG1755S)
BOSWELLIA SERRATA GUM (UNII: 4PW41QCO2M)
XANTHAN GUM (UNII: TTV12P4NEE)
TROLAMINE (UNII: 9O3K93S3TK)
METHYLPARABEN (UNII: A2I8C7HI9T)
PROPYLPARABEN (UNII: Z8IX2SC1OH)
DMDM HYDANTOIN (UNII: BYR0546TOW)
STEARYL ALCOHOL (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 Drug	M017	03/13/2013	

Labeler - A-S Medication Solutions (830016429)

Establishment

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