

NEW TEROGIN- methyl salicylate, capsaicin, and menthol lotion
Alexso 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.

New Terocin Topical Pain Relief Lotion

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.

Package/Label Principal Display Panel

NDC 50488-1129-1

New Terocin

Topical Pain
Relief Lotion

Long Lasting
Soothing Effect

120 ml (4 fl oz.)

Manufactured for: Alexso Inc.
Los Angeles, CA 90064

Store in a dry, cool place

Made in U.S.A.
Patent Pending

For Comments or Questions,
call 888-495-6075

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Soothing Effect

120 ml (4 fl oz.)



Drug Facts

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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:
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 Rev 08/22

Label

NEW TEROCIN		
methyl salicylate, capsaicin, and menthol lotion		
Product Information		
Product Type	HUMAN OTC DRUG	Item Code (Source) 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 VERA LEAF (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 STEARATE (UNII: YD01N1999R)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
POLYSORBATE 60 (UNII: CAL22UVI4M)
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)
LAVENDER OIL (UNII: ZBP1YXW0H8)
BORAGE SEED OIL (UNII: F8XAG1755S)
INDIAN FRANKINCENSE (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:50488-1129-1	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/13/2013	

Marketing Information

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

Labeler - Alexso Inc. (963338061)