

NEW TEROGIN- methyl salicylate, capsaicin, and menthol lotion
Aidarex Pharmaceuticals 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.

New Terocin 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

NDC 53217-0004-01

New Terocin

Topical Pain

Relief Lotion

Long Lasting

Soothing Effect

120 ml (4 fl oz.)

Manufactured for: Alexso Inc.

Thousand Oaks, CA 91360

Made in U.S.A.

Patent Pending

Repackaged By :

Aidarex Pharmaceuticals LLC,

Corona, CA 92880

Store in a dry, cool place

For Comments or Questions,

call 888-495-6075

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT KEEP OUT OF REACH OF CHILDREN. STORE AT CONTROLLED ROOM TEMP 15-30C (59-86F)

Packaged and Distributed by: **AIDAREX PHARMACEUTICALS LLC.**

TEROCIN LOTION

25/0.025/10%

120ml

CONTAINS THE FOLLOWING ACTIVE INGREDIENTS:
METHYL SALICYLATE.....25%
CAPSAICIN.....0.025%
MENTHOL.....10%

RX 1000966176

NDC: 53217-0004-01
APPLY _____ TIMES DAILY
APLIQUE _____ VECES AL DIA
MFG: FOR: ALEXSO INC. THOUSAND OAKS, CA 91360

TEROCIN LOTION
25/0.025/10%
NDC: 53217-0004-01
RX 1000966176 120ml

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RX 1000966176 120ml

PATIENT LOG CHART BILL
PEEL HERE

NEW TEROCIN

methyl salicylate, capsaicin, and menthol lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53217-004(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
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)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53217-004-01	120 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	03/13/2013	

Labeler - Aidarex Pharmaceuticals LLC (801503249)

Revised: 10/2013

Aidarex Pharmaceuticals LLC