TEROCIN- methyl salicylate, capsaicin, menthol and lidocaine hydrochloride lotion
Preferred Pharmaceuticals, 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.

Terocin Topical Pain Relief Lotion

Active ingredient

Methyl Salicylate 25%

Capsaicin 0.025%

Menthol 10%

Lidocaine 2.50%

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), Propylene Glycol, Cetyl Alcohol, Stearic Acid, Glyceryl Stearate, PEG-100 Stearate, Dimethyl Sulfone, Aloe Barbadensis Leaf Extract, Borago Officinalis Seed Oil, Boswellia Serrata Extract, Xanthan Gum, Triethanolamine,

Methylparaben, Propylparaben, DMDM Hydantoin, Iodopropynyl Butylcarbamate.

Package/Label Principal Display Panel

NDC 68788-9496-1

Terocin (terodoloricin) Topical Pain Relief Lotion

Long Lasting

Soothing Effect

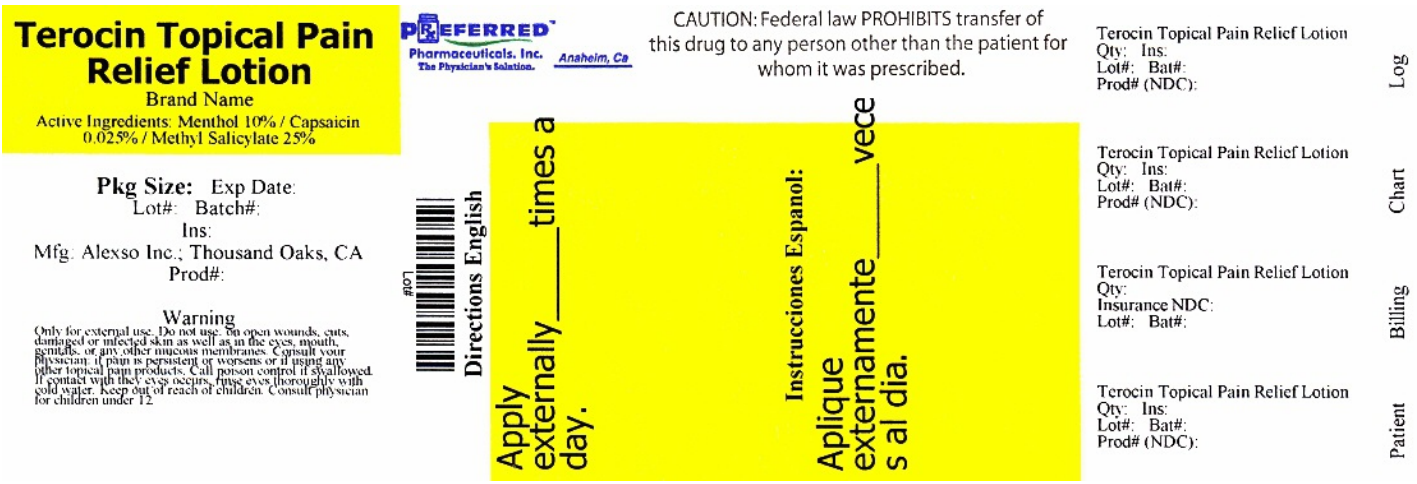
120 ml (4 fl oz.)

Manufactured for: Alexso Inc.

Thousand Oaks, CA 91360

Made in U.S.A.

Patent Pending



Package Label

TEROCIN

methyl salicylate, capsaicin, menthol and lidocaine hydrochloride lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68788-9496(NDC:50488-1231)
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
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	2.5 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)	
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:68788-9496-1	120 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/20/2014	

Labeler - Preferred Pharmaceuticals, Inc. (791119022)

Establishment

Name	Address	ID/FEI	Business Operations
Preferred Pharmaceuticals, Inc.		791119022	RELABEL(68788-9496)

Revised: 3/2014 Preferred Pharmaceuticals, Inc.