TEROCIN- methyl salicylate, capsaicin, menthol and lidocaine hydrochloride lotion
Unit Dose Services

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.
- on open wounds, cuts, damaged or infected skin as well as in the eyes, mouth, genitals, or any other mucous membranes. **Do not use:**
- if pain is persistent or worsens or if using any other topical pain products. **Consult your physician:**
- 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.

TEROCIN (METHYL SALICYLATE, CAPSAICIN, MENTHOL AND LIDOCAINE HYDROCHLORIDE) LOTION

TEROCIN

methyl salicylate, capsaicin, menthol and lidocaine hydrochloride lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50436-9995(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	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:50436-9995-1	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	10/01/2010	

Labeler - Unit Dose Services (831995316)

Registrant - Unit Dose Services (831995316)

Establishment

Name	Address	ID/FEI	Business Operations
Unit Dose Services		831995316	REPACK(50436-9995)

Revised: 10/2010   Unit Dose Services