

LIMENCIN- methyl salicylate, capsaicin, 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.

Limencin 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.

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 Barbadensis Leaf Extract, Borago Officinalis Seed Oil, Boswellia Serrata Extract, Xanthan Gum, Triethanolamine, Methylparaben, Propylparaben, DMDM Hydantoin, Iodopropynyl Butylcarbamate

PRINCIPAL DISPLAY PANEL

NDC 50488-1130-1

Limencin Lotion
Topical Pain Relief
Long Lasting
Soothing Effect
120 ml (4 fl oz.)

Manufactured for: Alexso, Inc.

Los Angeles, CA 90064

Store in a dry, cool place
For Comments or Questions,
call 888.495.6078

Made in the U.S.A.
Patent Pending

Label

LIMENCIN

methyl salicylate, capsaicin, menthol lotion

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:50488-1130 |
| 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) | |
| CETYL ALCOHOL (UNII: 936JST6JCN) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| PEG-100 STEARATE (UNII: YD01N1999R) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| DIMETHYL SULFONE (UNII: 9H4PO4Z4FT) | |
| LAVENDER OIL (UNII: ZBP1YXW0H8) | |
| LIDOCAINE (UNII: 98PI200987) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| BORAGE SEED OIL (UNII: F8XAG1755S) | |
| INDIAN FRANKINCENSE (UNII: 4PW41QCO2M) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |
| METHYL PARABEN (UNII: A2I8C7HI9T) | |
| PROPYL PARABEN (UNII: Z8IX2SC1OH) | |
| DMDM HYDANTOIN (UNII: BYR0546TOW) | |
| IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:50488-1130-1 | 120 mL in 1 BOTTLE; Type 0: Not a Combination Product | 10/01/2018 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part348 | 10/01/2018 | |

Labeler - Alexso, Inc. (963338061)