

EXOTEN-C- methyl salicylate, menthol, capsaicin lotion
Asclemed USA, Inc.

Drug Facts

Active Ingredients

Methyl Salicylate 20.000%

Menthol 10.00%

Capsaicin 0.025%

Purpose

Topical Analgesic

Topical Analgesic

Topical Analgesic

Indications

For the temporary relief of minor aches and pains of the muscles and joints associated with arthritis, simple backache, sprains, bruises and strains.

Warnings

For external use only. Avoid contact with eyes.

If symptoms persist for more than seven days, discontinue use and consult physician.

Keep out of reach of children. If swallowed, consult physician.

Do not apply to wounds or damaged skin. Do not bandage tightly.

If pregnant or breast feeding, contact physician prior to use.

Directions

Adults and children two-years of age or older: Apply to affected area not more than three to four times daily.

Children under two-years of age consult a physician.

Additional Information

Store at room temperature.

Other Ingredients

Aloe Barbadensis Leaf (Aloe Vera Gel) Juice; Aqua (Deionized Water); Arnica Montana Flower Extract; Carbomer, Cetearyl Alcohol, Ethylexyl Palmitate, Glyceryl Stearate, Methylisothiazolinone, PEG-100 Stearate, Tocopheryl Acetate (Vitamin E), Triethanolamine.

Principal Display Panel - Exoten-C Label

Exoten-C

Pain Relief Lotion

113.4 g

Distributed by Enovachem™

PHARMACEUTICALS

Torrance, CA 90501

(310) 320-0100

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NDC 76420-947-01

EXOTEN-C

methyl salicylate, menthol, capsaicin lotion

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:76420-947 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|------------------|
| METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ) | METHYL SALICYLATE | 20 g in 100 g |
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 10 g in 100 g |
| CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM) | CAPSAICIN | 0.025 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|-----------------|
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| WATER (UNII: 059QF0KO0R) | |
| ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ) | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | |
| ETHYLHEXYL PALMITATE (UNII: 2865993309) | |
| GLYCERYL STEARATE SE (UNII: FCZ5MH785I) | |
| METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA) | |
| PEG-100 STEARATE (UNII: YD01N1999R) | |
| .ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|--|-----------------------------|---------------------------|
| 1 | NDC:76420-947-01 | 113.4 g in 1 BOTTLE; Type 0: Not a Combination Product | 02/10/2017 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| OTC Monograph Drug | M017 | 02/10/2017 | |

Labeler - Asclemed USA, Inc. (059888437)