

MENTHOL, LIDOCAINE, CAMPHOR- menthol, lidocaine, camphor gel

CHEMCO CORPORATION

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.

49283-541-03

AlfleXil®
ZERO PAIN
ROLL-ON

- Menthol 11%
- Lidocaine
- Camphor
- Arnica
- Glucosamine
- Chondroitin

Pain relief
 Analgesic
 Healthy Joints

NET WT. 3.18 oz (90 g)

Drug Facts

ACTIVE INGREDIENTS/PURPOSE:
Menthol 11% Topical Analgesic
Lidocaine 4% Topical Analgesic
Camphor 0.5% Pain Relieving

USES:
• For temporary local relief of minor pain in muscles or joints.
• For external use only.

WARNINGS:
• For external use only.

WHEN USING THIS PRODUCT:
• Use only as directed.
• Do not bandage tightly or use with a heating pad.
• Avoid contact with eyes and mucous membranes.
• Do not apply to wounds or damaged, broken or irritated skin.
• A stinging or tingling sensation or redness may occur upon application but generally disappears in several days.
• If skin experiences an allergic reaction, discontinue use and consult a physician.
• Do not expose the area treated with product to heat or direct sunlight.

FLAMMABLE:
Keep away from fire or flame.

IF PREGNANT OR BREAST-FEEDING:
Ask a health professional before use.

KEEP OUT OF REACH OF CHILDREN:
If swallowed, get medical help or contact a Poison Control Center right away.

STOP USE AND ASK A DOCTOR IF:
• Condition worsens
• Rashness is present
• Irritation develops
• Symptoms persist for more than 7 days or clear up occur again within a few days
• You experience signs of injury, such as pain, swelling or blistering where the product was applied.

Processed under the highest standards of quality assurance and Good Manufacturing Practices.

Drug Facts (Continued)

DIRECTIONS:
Adults and Children over 12 years:
• Apply a small amount to the area.
• Massage in a circular motion. Let set for a few seconds.
• Repeat as necessary, but no more than 3 to 4 times daily.
• Store tightly closed in a dry place at controlled room temperature between 59° F (15°-20° C).

QUESTION OR COMMENTS?
info@alfavitamins.com

INACTIVE INGREDIENTS:
• Aqua, Alcohol Denat., Ammonium Benzoate, Flavor Extract, Colophonyl-20, Propylene Glycol, Tetrahydrocannabinol, Calcium Chloride, Methyl Salicylate, Sodium Chondroitin Sulfate, Dicalcium EDTA, Glucosamine Sulfate, Terephthalic Acid, Rosinamide, Ethylmethylphenylacetate, Methylphenylacetate, PEG-40 Stearoyl Ether (D-4200).

NDC# 49283-541-03

EXTRA STRENGTH
IMMEDIATE ACTION
FAST ACTING FORMULA

Manufactured by:
Chemco, Florida 33014

ALFA
Distributed by
ALFA VITAMINS LABORATORIES, INC.
4201 N.W. 77th Ave., Miami, FL 33150
info@alfavitamins.com

MENTHOL, LIDOCAINE, CAMPHOR

menthol, lidocaine, camphor gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:49283-541 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------|----------------|
| LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987) | LIDOCAINE | 4 g in 100 g |
| CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET) | CAMPHOR (SYNTHETIC) | 0.5 g in 100 g |
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 11 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| WATER (UNII: 059QF0KO0R) | |
| ALCOHOL (UNII: 3K9958V90M) | |
| CARBOMER 940 (UNII: 4Q93RCW27E) | |
| METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA) | |
| METHYL SALICYLATE (UNII: LAV5U5022Y) | |
| BASIC BLUE 1 (UNII: 92N74OA24D) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| SODIUM CHONDROITIN SULFATE (PORCINE; 5500 MW) (UNII: H5BJH23Z9A) | |
| GLUCOSAMINE SULFATE (UNII: 1FW7WLR731) | |
| ROSMARINUS OFFICINALIS FLOWERING TOP (UNII: 8JM482TI79) | |
| METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN) | |
| ARNICA MONTANA FLOWER WATER (UNII: U7L2JP51PR) | |

Product Characteristics

| | | | |
|-----------------|------|---------------------|--|
| Color | blue | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:49283-541-03 | 90 g in 1 BOTTLE; Type 0: Not a Combination Product | 07/27/2021 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part346 | 07/27/2021 | |

Labeler - CHEMCO CORPORATION (032495954)

Registrant - CHEMCO CORPORATION (032495954)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------|---------|-----------|------------------------|
| CHEMCO CORPORATION | | 032495954 | manufacture(49283-541) |