

MENTHOL, CAMPHOR- menthol, camphor gel
SUNSET NOVELTIES, 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.

72937-600-17

Menthol 6%

Camphor 2%

Topical Analgesic

Pain Relieving

USES:

Aid for temporary local relief of minor pain in muscles or joints.

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 transient burning sensation or redness may occur upon application but generally disappears in several days

If you experience an allergic reaction, discontinue use, and consult a physician

Do not expose the area treated with product to heat or direct sunlight.

If swallowed, get medical help or contact a Poison Control Center right away.

Ask a health professional before use.

Condition worsens

Redness is present

Irritation develops

Symptoms persist for more than 7 days or clear up occur again within a few days

You experience signs injury, such as pain, swelling or blistering where the product was applied.

DIRECTIONS:

Adults and Children over 12 years:

Apply a small amount on the area to be.

Massaged in a circular motion until absorbed.

Repeat as needed, but no more than 3 to 4 times per day.

Store tightly closed in a dry place at room temperature between 59°-86° F (15°-30° C).

Wash hands with soap and water after use.

Aqua, Alcohol Denat, Propylene Glycol, Salicylic Acid, Glycerin, Polysorbate 20, Carbomer, Sodium Hydroxide, Mentha Arvensis Herb Oil, Rosmarinus Officinalis (Rosemary) Oil, Thymus Vulgaris (Thyme) Oil, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Cannabis Sativa Seed Oil, Benzyl Alcohol, Sorbic Acid, Cannabidiol, FD&C Blue. 1 Powder (CI 42090), FD&C Yellow. 5 (CI 19140).

GREEN FARM COOLING RELIEF GEL 1.7oz

DRUG FACTS

ACTIVE INGREDIENT

Menthol — 6% Topical Analgesic
Camphor — 2% Pain Relieving

USES: Aid for temporary local relief of minor pain in muscles or joints.

WARNINGS: For external use only.

WHEN USING THIS PRODUCT

- Use only as directed
- Do not massage lightly 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 transient burning sensation or redness may occur upon application but generally disappears in several days
- If you experience an allergic reaction, discontinue use, and consult a physician
- Do not expose the area treated with product to heat or direct sunlight.

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
- Redness is present
- Irritation develops
- Symptoms persist for more than 7 days or clear up occur again within a few days
- You experience signs injury, such as pain, swelling or blistering where the product was applied.

DIRECTIONS: Adults and Children over 12 years:

- Apply a small amount on the area to be.
- Massaged in a circular motion until absorbed.
- Repeat as needed, but no more than 3 to 4 times per day.
- Store tightly closed in a dry place at room temperature between 59-86° F (15°-30° C).
- Wash hands with soap and water after use.

INACTIVE INGREDIENTS:
Aqua, Alcohol Denat, Propylene Glycol, Salicylic Acid, Glycerin, Polysorbate 20, Carbomer, Sodium Hydroxide, Mentha Arvensis Herb Oil, Rosmarinus Officinalis (Rosemary) Oil, Thymus Vulgaris (Thyme) Oil, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Cannabis Sativa Seed Oil, Benzyl Alcohol, Sorbic Acid, Cannabidiol, FD&C Blue. 1 Powder (CI 42090), FD&C Yellow. 5 (CI 19140).

GREEN FARM
CBD INFUSED PRODUCTS

CBD COOLING RELIEF GEL
ULTRA STRENGTH

+500

NET WT
1.7 FL OZ / 50ML

www.sunsetcbdtemp.com
NDC: 72937-600-17

MENTHOL, CAMPHOR

menthol, camphor gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:72937-600 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|--------------|
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 6 g in 100 g |

CAMPHOR, (-)- (UNII: 213N3S8275) (CAMPHOR, (-)- - UNII:213N3S8275)

CAMPHOR, (-)-

2 g in 100 g

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| CANNABIDIOL (UNII: 19GBJ60SN5) | |
| MENTHA ARVENSIS LEAF OIL (UNII: 1AEY1M553N) | |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) | |
| CARBOMER 940 (UNII: 4Q93RCW27E) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| SALICYLIC ACID (UNII: O414PZ4LPZ) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| POLYSORBATE 20 (UNII: 7T1F30V5YH) | |
| ROSMARINUS OFFICINALIS FLOWERING TOP OIL (UNII: OXN0D3N28L) | |
| SORBIC ACID (UNII: X045WJ989B) | |
| WATER (UNII: 059QF0KO0R) | |
| BENZYL ALCOHOL (UNII: LKG8494WBH) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |
| THYMUS VULGARIS LEAF (UNII: GRX3499643) | |
| MELALEUCA ALTERNIFOLIA FLOWERING TOP (UNII: 5AZ4S6N66F) | |
| CANNABIS SATIVA SEED OIL (UNII: 69VJ1LPN1S) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| ALCOHOL (UNII: 3K9958V90M) | |

Product Characteristics

| | | | |
|----------|-------------------|--------------|--|
| Color | white (Turquoise) | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:72937-600-17 | 48 g in 1 BOTTLE; Type 0: Not a Combination Product | 09/22/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part348 | 09/22/2020 | |

Labeler - SUNSET NOVELTIES, INC (067218145)

