HEATING PAIN RELIEF- methyl salicylate, menthol cream SUNSET NOVELTIES, INC

72937-180-40 72937-180-80

Methyl Salicylate 18%

Menthol 10%

Topical Analgesic.

USES:

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

For external use only. · Ask a doctor before use if you have redness over affected area

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

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

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

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.

IF PREGNANT OR BREAST - FEEDING:

Ask a health professional before use.

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

DIRECTIONS:

Adults and Children over 12 years

Apply a small amount on the affected area.

Massage in circular motion, let set for a few seconds..

Repeat as necessary, but no more than 3 to 4 times daily.

Wash hands with soap and water after use.

Children under 12 years of age consult a doctor.

Store tightly closed in a dry place at controlled room temperature between $59^{\circ}-86^{\circ}$ F ($15^{\circ}-30^{\circ}$ C).

Inactive Ingredients

Water (Aqua), Paraffinum Liquidum, Glyceryl Stearate, Stearic Acid, Cetyl Alcohol, Dimethicone, Glycereth-26, Acrylamide/Sodium Acrylate Copolymer, Trideceth-6, Caprylyl Glycol, Phenoxyethanol, Hexylene Glycol, Stearyl Alcohol, Triethanolamine, Sodium Hyaluronate, Sodium PCA, Wheat Amino Acids, Panthenol, Symphytum Officinale (Comfrey) Extract, Hydroxyproline, Cannabidiol, FD&C Yellow No.6 (CI 15985).

SUNSET - HEATING PAIN RELIEF CREAM 4 oz TUBE



SUNSET - HEATING PAIN RELIEF CREAM 8 oz TUBE

Drug Facts

Active ingredients

Purpose Menthol 10% Topical Analgesic Methyl Salicylate 18% Topical Analgesic

Aid for temporary local relief of minor pain in muscles or

Warnings

For external use only. • Ask a doctor before use if you have redness over affected area.

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

 If you experience an allergic reaction, discontinue use, a consult a physician
- Do not expose the area treated with product to heat or direct sunlight.

Stop use and ask a doctor if

- Condition worsens
- Redness is presentIrritation 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.

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.

Adults and Children over 12 years

- Apply a small amount on the affected area.
- sage in circular motion, let set for a few seconds. Repeat as necessary, but no more than 3 to 4 times
- · Wash hands with soap and water after use

Children under 12 years of age consult a doctor.

Other information

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

Inactive Ingredients

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Water (Aqua), Paraffinum Liquidum, Glyceryl Stearate,
Stearic Acid, Cetyl Alcohol, Dimethicone, Glycereth-26,
Acrylamide/Sodium Acrylate Copolymer, Trideceth-6,
Caprylyl Glycol, Phenoxyethanol, Hexylene Glycol, Stearyl
Alcohol, Triethanolamine, Sodium Hyaluronate, Sodium
PCA, Wheat Amino Acids, Panthenol, Symphytum Officinale
(Comfrey) Extract, Hydroxyproline, Cannabidiol, FD&C
Yellow No.6 (Cl 15985).

*This statement has not been evaluated by the Food and Drug Administration (FDA). This product is not intended to diagnose, treat, cure or prevent any dise

LESS THAN 0.3% THC MADE IN USA

Exclusively Distributed by: ${\bf SUNSET\ NOVELTIES.}$

5700 PEMBROKE RD WEST PARK, FL 33023. **(888) 367 4916.**

www.sunsetcbdhemp.com









MENTHOL & AMINO ACIDS TARGETED HEAT RELIEF OF SORE MUSCLES

ULTRA STRENGTH

+Menthol

8 FL OZ | 236 ML

HEATING PAIN RELIEF

methyl salicylate, menthol cream

Product Information

Product Type HUMAN OTC DRUG **Item Code (Source)** NDC:72937-180

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Basis of Ingradiant Nam

| ingrealent Name | Strength | strength |
|--|-------------------|---------------------|
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 9.8 g in 100 mL |
| METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII: O414PZ4LPZ) | METHYL SALICYLATE | 17.6 g in 100 mL |

| Inactive Ingredients | | |
|---|----------|--|
| Ingredient Name | Strength | |
| GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4) | | |
| CETYL ALCOHOL (UNII: 936JST6JCN) | | |
| GLYCERETH-26 (UNII: NNE56F2N14) | | |
| TRIDECETH-6 (UNII: 3T5PCR2H0C) | | |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) | | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | | |
| COMFREY LEAF (UNII: DG4F8T839X) | | |
| CANNABIDIOL (UNII: 19GBJ60SN5) | | |
| WATER (UNII: 059QF0KO0R) | | |
| HYALURONATE SODIUM (UNII: YSE9PPT4TH) | | |
| AMINO ACIDS, WHEAT (UNII: 0370GZL32F) | | |
| PANTHENOL (UNII: WV9CM0O67Z) | | |
| HYDROXYPROLINE (UNII: RMB44WO89X) | | |
| HEXYLENE GLYCOL (UNII: KEH0A3F75J) | | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | | |
| DIMETHICONE 1000 (UNII: MCU2324216) | | |
| STEARYL ALCOHOL (UNII: 2KR89I4H1Y) | | |
| TROLAMINE (UNII: 903K93S3TK) | | |
| SODIUM PYRROLIDONE CARBOXYLATE (UNII: 4690TG57A2) | | |
| MINERAL OIL (UNII: T5L8T28FGP) | | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | | |

| Product Characteristics | | | |
|-------------------------|-----------------------|--------------|--|
| Color | orange (Light Orange) | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

| P | Packaging | | | | |
|---|----------------------|---|-------------------------|-----------------------|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 | NDC:72937-180- 40 | 118 mL in 1 TUBE; Type 0: Not a Combination Product | 06/26/2023 | | |
| 2 | NDC:72937-180- 80 | 236 mL in 1 TUBE; Type 0: Not a Combination Product | 06/26/2023 | | |

| Marketing Information | | | |
|-----------------------|---------------------------------|-----------------|---------------|
| Marketing | Application Number or Monograph | Marketing Start | Marketing End |
| Category | Citation | Date | Date |

OTC Monograph Drug M017

05/25/2023

Labeler - SUNSET NOVELTIES, INC (067218145)

Revised: 2/2024 SUNSET NOVELTIES, INC