

HEATING PAIN RELIEF- methyl salicylate, menthol cream
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.

72937-180-02
72937-180-04
72937-180-08
72937-180-16

Menthol 10%

Methyl Salicylate 18%

Topical Analgesic.

USE

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°-86° F (15°-30° C).

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 2 oz

<p>Drug Facts</p> <p>Active ingredients Methyl Salicylate 18%.....</p> <p>Purpose Topical Analgesic Topical Anesthetic</p> <p>Use Aid for temporary local relief of minor pain in muscles or joints.</p> <p>Warnings • For external use only • Ask a doctor before use if you have redness over affected area</p> <p>When using this product • 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.</p> <p>Stop use and ask a doctor if • Condition worsens • Redness is present • Irritation develops • Symptoms persist for more than 7 days or clear up or occur again within a few days • You experience signs injury, such as pain, swelling or blistering where the product was applied.</p>	 <p>SUNSET CBD PAIN RELIEF CREAM + 250 CBD OIL MENTHOL & AMINO ACIDS TARGETED HEAT RELIEF OF SORE MUSCLES 250 ULTRA STRENGTH +Menthol 2 FL OZ</p>	<p>Drug Facts (continued)</p> <p>If pregnant or breast-feeding • Ask a health professional before use.</p> <p>Keep out of reach of children If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>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</p> <p>Other information Store tightly closed in a dry place at controlled room temperature between 59°-86° F. (15°-30° C).</p> <p>Contains the following 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).</p> <p>Exclusively Distributed by: SUNSET NOVELTIES, 5700 PERDISCO RD WEST PALM FL, 33413. (888) 367-4916, www.sunsetcbd.com LESS THAN A TWEED SHAVE IN USA</p>

SUNSET - HEATING PAIN RELIEF CREAM 4 oz

Drug Facts Active Ingredients Menthol 10% Methyl Salicylate 16% Use For temporary local relief of minor pain in muscles or joints. 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 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. Stop use and ask a doctor if • Condition worsens. • Redness is present. • Irritation develops. • Symptoms persist for more than 7 days or clear up again within a few days. • You experience signs injury, such as pain, swelling or blistering where the product was applied.	 <p>SUNSET CBD</p> <p>HEATING PAIN RELIEF CREAM +500 CBD OIL</p> <p>MENTHOL & AMINO ACIDS</p> <p>TARGETED HEAT RELIEF OF SORE MUSCLES</p> <p>ULTRA STRENGTH</p> <p>• Menthol 4 FL OZ</p>	Drug Facts (continued) 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. Directions Adults and Children over 12 years • Apply a small amount on the affected area. • Massage in circular motion, let set for 1 to 5 seconds. • Repeat as necessary, but no more than 3 to 4 times daily. • Wash hands with soap and water after use. Other information Store at 20° to 25° (68° to 77° F) in a dry place at controlled room temperature between 59° and 86° F (15° and 30° C). Inactive Ingredients Water (Aqua), Propylene Glycol, Polyethylene Glycol, Glycerol Stearate, Stearic Acid, Cetyl Alcohol, Dimethylsiloxane, Polydimethylsiloxane, Acrylamide Copolymer, Triethylcitrate, Citric Acid, Phosphoric Acid, Hydroxyethyl Cellulose, Benzyl Alcohol, Hydroxyethylamine, Sodium Hydroxide, Sodium Acrylate, Water, Acetic Acid, Parabens, Synthetic Fragrance, Carbonyl Lactate, Hydroxypropyl, Carbamide, FD&C Yellow No. 6 (CI 15985). <small>Exclusively Distributed by: SUNSET NOVELTIES, 5700 PENNSACKE RD, WEST PALM, FL 33413, (888) 367-4916, www.sunsetcbd.com ©2021 SUNSET, INC. MADE IN USA</small>	 
		<small>ND-C-73937-18-04</small>	<small>*This statement has not been evaluated by the Food and Drug Administration. It is not intended to diagnose, cure, treat, or prevent any disease.</small>

SUNSET - HEATING PAIN RELIEF CREAM 8 oz

Drug Facts	Active Ingredients	Purpose
	Menthol 10% Methyl Salicylate 16%	Topical Anesthetic Topical Analgesic
Warnings	<p>Use only for temporary local relief of minor pain in muscles or joints.</p> <p>For external use only. • Ask a doctor before use if you have redness over affected area.</p> <p>When using this product:</p> <ul style="list-style-type: none"> • Use only as directed • Do not repackage, 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. <p>Stop use and ask a doctor if:</p> <ul style="list-style-type: none"> • 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. 	
 <p>SUNSET CBD</p> <p>HEATING PAIN RELIEF CREAM + 1000 CBD OIL</p> <p>MENTHOL & AMINO ACIDS</p> <p>TARGETED HEAT RELIEF OF SORE MUSCLES</p> <p>ULTRA STRENGTH</p> <p>+ Menthol</p> <p>8 FL. OZ</p>		
<p>Directions</p> <p>Apply to sore muscles or joints over 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</p> <p>Children under 12 years of age: consult a doctor</p> <p>Other information</p> <p>Store tightly closed in a dry place at controlled room temperature between 59°-86° F (15°-32° C)</p> <p>Inactive Ingredients</p> <p>Water, Ethyl, Palmitic Acid, Lauric Acid, Glycerol Stearate, Stearic Acid, Cetyl Alcohol, Dimethylsiloxane, Glycol Stearate, Acrylamide/Sodium Acrylate Copolymer, Triethoxy-Silicate, Cellulose, Hydroxyethylcellulose, Stearic Acid, Stearyl Alcohol, Hydroxyethylcellulose, Sodium Hydroxide, Sodium PCA, Wheat Amino Acids, Panthenol, Symphytum Officinale (Comfrey) Extract, Lactococcus, Camphor, PEG, Yellow No. 6 (C.I. 15850)</p> <p>Exclusively Distributed by: SUNSET NOVELTIES, 5700 HENRIE RD, WEST PALM, FL 33411 (888) 367-4916, www.sunsetcbd.com LESS THAN A PENNY THE DIFFERENCE MADE IN USA</p>		

SUNSET - HEATING PAIN RELIEF CREAM 16 oz



Drug Facts

Active Ingredients
 Menthol 10% Topical Analgesic
 Methyl Salicylate 18% Topical Analgesic

Purpose
 Topical Analgesic

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

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

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.

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.

HEATING PAIN RELIEF CREAM+3000 CBD OIL
MENTHOL & AMINO ACIDS
 TARGETED HEAT RELIEF OF SORE MUSCLES
ULTRA STRENGTH
 + Menthol
 16 FL OZ

Drug Facts (continued)

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.

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.

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

Inactive Ingredients
 Water (Aqua), Paraffinum Liquidum, Glycerol Stearate, Stearic Acid, Cetyl Alcohol, Dimethicone, Glycereth-26, Acrylates/Sodium Acrylate Copolymer, Triisobutyl-Carbitol, Phenoxyethanol, Hexylene Glycol, Stearyl Alcohol, Triethanolamine, Sodium Myristate, Sodium PCA, Wheat Amino Acids, Fragrance, Symphytum officinale (Comfrey) Extract, Hydroxypropyltrimethylammonium Chloride, FD&C Yellow No.6 (CI 15985).

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 (855) 367-4916, www.sunsetcbd.com

LESS THAN 0.2% THC. MADE IN USA.

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

Ingredient Name	Basis of 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: 230OU9XXE4)	
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: WW9CM0067Z)
HYDROXYPROLINE (UNII: RMB44WO89X)
HEXYLENE GLYCOL (UNII: KEH0A3F75J)
STEARIC ACID (UNII: 4ELV7Z65AP)
DIMETHICONE 1000 (UNII: MCU2324216)
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)
TROLAMINE (UNII: 9O3K93S3TK)
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)
MINERAL OIL (UNII: T5L8T28FGP)
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)

Product Characteristics

Color	orange	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72937-180-02	60 mL in 1 JAR; Type 0: Not a Combination Product	09/15/2023	
2	NDC:72937-180-04	118 mL in 1 JAR; Type 0: Not a Combination Product	09/15/2023	
3	NDC:72937-180-08	237 mL in 1 JAR; Type 0: Not a Combination Product	09/15/2023	
4	NDC:72937-180-16	473 mL in 1 JAR; Type 0: Not a Combination Product	09/15/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/15/2023	

Labeler - SUNSET NOVELTIES, INC (067218145)