

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.

72937-006-02
72937-006-04
72937-006-08
72937-006-16

Camphor 2%

Menthol 6%

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

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.

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), Alcohol Denat, Propylene Glycol, Polysorbate 20, Carbomer, Sodium Hydroxide, Salicylic Acid, Glycerin, Mentha Piperita (Peppermint) 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 No. 1 (CI 42090), FD&C Yellow No.5 (CI 19140).

SUNSET - COOLING PAIN RELIEF GEL 2oz

Drug Facts Active Ingredients Menthol Methyl Salicylate Topical Anesthetic Ethyl Alcohol Warnings For temporary local relief of minor pain in muscles or joints. Directions For external use only. Ask a doctor before use if you have redness over affected area. When using this product Do not use if redness, irritation, or rash is present. Avoid contact with eyes, nose, mouth, or open wounds. Do not use on children under 12 years of age. If symptoms persist for more than 7 days, or clear up or recur again within a few days, stop use and ask a doctor. Stop use and ask a doctor if • Redness is present • Irritation develops • Symptoms persist for more than 7 days or clear up or recur again within a few days • You experience an allergic reaction to any of the ingredients listed on the label • You have an allergic reaction to any of the ingredients listed on the label • You have a history of allergic reactions to any of the ingredients listed on the label • You have a history of allergic reactions to any of the ingredients listed on the label	 <p>SUNSET PAIN RELIEF GEL + 250 CBD OIL ROSEMARY & THYME EXTRACT ULTRA STRENGTH Tea • Mint 2 FL OZ</p>	Drug Facts (continued) Directions If pregnant or breastfeeding • Ask a health professional before use. Warnings • Do not use if redness, irritation, or rash is present. Directions • Adults and Children over 12 years: Apply a small amount to 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). Other ingredients Water (Aqua), Alcohol Denat, Propylene Glycol, Polysorbate 20, Carbomer, Sodium Hydroxide, Salicylic Acid, Glycerin, Mentha Piperita (Peppermint) 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 No. 1 (CI 42090), FD&C Yellow No. 5 (CI 19140). ©2022 Sunset Pharmaceuticals, LLC. All rights reserved. Sunset Pharmaceuticals, LLC. 10001 Sunset Blvd, Suite 100, San Diego, CA 92161. www.sunsetpharm.com. U.S. Patent # 10,582,307 #10. U.S. Patent # 10,582,307 #10. U.S. Patent # 10,582,307 #10.
	Other information Store tightly closed in a dry place at controlled room temperature between 59°-86° F (15°-30° C). Other ingredients Water (Aqua), Alcohol Denat, Propylene Glycol, Polysorbate 20, Carbomer, Sodium Hydroxide, Salicylic Acid, Glycerin, Mentha Piperita (Peppermint) 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 No. 1 (CI 42090), FD&C Yellow No. 5 (CI 19140). ©2022 Sunset Pharmaceuticals, LLC. All rights reserved. Sunset Pharmaceuticals, LLC. 10001 Sunset Blvd, Suite 100, San Diego, CA 92161. www.sunsetpharm.com. U.S. Patent # 10,582,307 #10. U.S. Patent # 10,582,307 #10. U.S. Patent # 10,582,307 #10.	

SUNSET - COOLING PAIN RELIEF GEL 4oz

Drug Facts	
Active Ingredients	Purpose
Capsaicin 2%	Topical Analgesic
Menthol 6%	Topical Anesthetic
Use	
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	
<ul style="list-style-type: none"> 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	
<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 of injury, such as pain, swelling or blistering where the product was applied. 	
 <p>PAIN RELIEF GEL + 500 CBD OIL *</p> <p>ROSEMARY & THYME EXTRACT</p> <p>TEMPORARY COOLING RELIEF OF SORE MUSCLES</p> <p>ULTRA STRENGTH</p> <p>* Tea Tree • Mint</p> <p>4 FL OZ</p>	
<small>*This statement has not been evaluated by the Food and Drug Administration and is not intended to diagnose, cure, treat, or prevent any disease.</small>	
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	
<ul style="list-style-type: none"> 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. 	
Other information	
<ul style="list-style-type: none"> Keep in a dry place at controlled room temperature between 59°F (15°C) and 86°F (30°C). 	
Inactive Ingredients	
Water, Glycerin, Alcohol Denat., Propylene Glycol, Polyorbate 20, Carbomer, Sodium Hydroxide, Salicylic Acid, Glycolic Acid, Mentha Viridis (Peppermint) Oil, Isoeucalyptol, 2-Hydroxyethyl Acrylate, Thymus Vulgaris (Thyme) Oil, Mentha Arvensis (Lemon Balm) Oil, Camphor, Juniperus Oil, Eucalyptus Oil, Citronellol, Citric Acid, Carbamide, FD&C Blue No. 1 (CI 42000), FD&C Yellow No. 5 (CI 19140).	
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SUNSET - COOLING PAIN RELIEF GEL 8oz



SUNSET CBD

PAIN RELIEF GEL+3000 CBD OIL *

ROSEMARY & THYME EXTRACT

TEMPORARY COOLING RELIEF OF SORE MUSCLES

ULTRA STRENGTH

+ Tea Tree + Mint

16 FL OZ

Drug Facts

Active Ingredients

Active Ingredient	Purpose
Camphor 2%	Topical Analgesic
Menthol 6%	Topical Anesthetic

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.

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), Alcohol Denat., Propylene Glycol, Polyorbate 20, Carbomer, Sodium Hydroxide, Salicylic Acid, Citron, Mentha Piperita (Peppermint) Oil, Rosmarinus Officinalis (Rosemary) Oil, Thymus Vulgaris (Thyme) Oil, Melissa Leuca Alternifolia (Tea Tree) Leaf Oil, Cannabis Sativa Seed Oil, Benzyl Alcohol, Sorbic Acid, Carnubolol, FD&C Blue No. 1 (CI 42000), FD&C Yellow No. 5 (CI 19140).

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0583 357 4916, www.sunsetcbd-shop.com LESS THAN 0.3% THC. MADE IN USA.

MENTHOL, CAMPHOR

menthol, camphor gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72937-006
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
MENTHA PIPERITA (UNII: 79M2M2UDA9)	
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)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
SORBIC ACID (UNII: X045WJ989B)	
WATER (UNII: 059QF0KO0R)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
THYME OIL (UNII: 2UK410MY6B)	
TEA TREE OIL (UNII: VIF565UC2G)	
CANNABIS SATIVA SEED OIL (UNII: 69VJ1LPN1S)	
ALCOHOL (UNII: 3K9958V90M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CANNABIDIOL (UNII: 19GBJ60SN5)	

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:72937-006-02	59 g in 1 BOTTLE; Type 0: Not a Combination Product	09/08/2022	
2	NDC:72937-006-04	118 g in 1 BOTTLE; Type 0: Not a Combination Product	09/08/2022	
3	NDC:72937-006-08	236 g in 1 BOTTLE; Type 0: Not a Combination Product	09/08/2022	
4	NDC:72937-006-16	472 g in 1 BOTTLE; Type 0: Not a Combination Product	09/08/2022	

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)