

MENTHOL- menthol gel
SUNSET PAIN RELIEF ROLL-ON 3OZ

72937-004-03

Menthol 4%

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.

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 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.

Children under 12 years of age: do not use, 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, Glycerin, Cetearth-25, Caprylic/Capric Triglyceride, Calendula Officinalis Extract, Benzyl Alcohol, Salicylic Acid, Sorbic Acid, Sodium Hydroxide, Carbomer, Cannabidiol, Methyl Salicylate.

SUNSET PAIN RELIEF +350 CBD ROLL-ON

Drug Facts

Active Ingredients:
Menthol 4%
Purpose: Topical Analgesic

Uses:
• Not 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 swell up or 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.

Directions:
Adults and Children over 12 years of age:
• Apply a small amount to the affected area. • Massage in circular motion, let rest for 2 to 3 seconds. • Repeat as necessary, but no more than 3 to 4 times daily.
Children under 12 years of age: do not use, 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), Atalaya Desert, Glycerin, Carbomer 25, Caprylic/Capric Triglyceride, Calendula Officinalis Extract, Benzyl Alcohol, Salicylic Acid, Sodium Acrylate, Sodium Hydroxide, Capromer, Carbomer 980, Methyl Salicylate.

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 disease.

ROLL-ON

Start with a small amount and monitor the pain before applying a larger amount.

3 OZ

NDC#: 72937-004-03

MENTHOL

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72937-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	4 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
CANNABIDIOL (UNII: 19GBJ60SN5)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	

GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
SORBIC ACID (UNII: X045WJ989B)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72937-004-03	90 mL in 1 BOTTLE, WTH APPLICATOR; Type 0: Not a Combination Product	09/24/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	09/24/2019	

Labeler - SUNSET PAIN RELIEF ROLL-ON 3OZ (067218145)

Revised: 1/2024

SUNSET PAIN RELIEF ROLL-ON 3OZ