GREEN FARM POTENT COOLING RELIEF- 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.

72937-026-02 72937-026-04 72937-026-08 72937-026-16

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.

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 transcient burning sensation or redness may occur upon application but generally dissapears 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.

Ask a health professional before use.

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

STOP USE AND ASK A DOCTOR IF:

Conditions worsen 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 desired area. Massage in circular motions until absorbed Repeat as necessary, but no more than 3 to 4 times per day. Store tightly closed in a dry place at controlled 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 (Cl 42090), FD&C Yellow. 5 (Cl 19140).

GREEN FARM POTENT COOLING RELIEF GEL 2 oz



GREEN FARM POTENT COOLING RELIEF GEL 4 oz



GREEN FARM POTENT COOLING RELIEF GEL 8 oz



GREEN FARM POTENT COOLING RELIEF GEL 16 OZ



GREEN FARM POTE	NT COOLING REL	JEF			
menthol, camphor gel					
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:72937-026	
Route of Administration	TOPICAL				
Active Ingradiant/Active	Maiaty				
Active Ingredient/Active	emolety				
Ing	redient Name		Basis Streng	•-	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) ME			MENTHOL		6 g in 100 mL
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - CAMPHOR (SYNTHETIC) - UNII: 5TJD82A1ET)				2 g in 100 mL	
Inactive Ingredients					
	Ingredient Name			St	rength
CARBOMER 940 (UNII: 4Q93RCW	27E)				
WATER (UNII: 059QF0KO0R)					

SODIUM HYDROXIDE (UNII: 55X04QC32I)

MENTHA ARVENSIS LEAF OIL (UNII: 1AEY1M553N)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
THYME OIL (UNII: 2UK410MY6B)	
TEA TREE OIL (UNII: VIF565UC2G)	
CANNABIS SATIVA SEED OIL (UNII: 69VJ1LPN1S)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SORBIC ACID (UNII: X045WJ989B)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: 1753WB2F1M)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ALCOHOL (UNII: 3K9958V90M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
CANNABIDIOL (UNII: 19GBJ60SN5)	

Product Characteristics

Color	turquoise	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72937-026- 02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2022	
2	NDC:72937-026- 04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2022	
3	NDC:72937-026- 08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2022	
4	NDC:72937-026- 16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2022	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC monograph not final	part348	12/05/2022	

Labeler - SUNSET NOVELTIES, INC (067218145)