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

SUNSET - HEATING PAIN RELIEF CREAM 4 oz

SUNSET - HEATING PAIN RELIEF CREAM 8 oz

SUNSET - HEATING PAIN RELIEF CREAM 16 oz

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: WV9CM0O67Z)	
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)