

DR WOLFES COOL THERAPY- menthol gel
SOMBRA COSMETICS 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.

Dr Wolfes Cool Therapy

Active Ingredients

Menthol USP 6%

Purpose

Purpose
External Analgesic

Keep out of reach of children

Keep out of reach of children

Uses

Temporarily relieves minor aches and pains of muscles and joints associated with: simple backaches, strains, bruises, and sprains

Warnings

For external use only. Do not use on wounds or damaged skin or with a heat source. **If pregnant or breastfeeding, consult a healthcare professional before use.** When using this product : avoid bandaging tightly, avoid contact with eyes, **Keep out of reach of children.**

Stop use and ask doctor if: condition worsens, symptoms persist for more than 7 days, symptoms clear up and occur again within a few days.

Directions

adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily, rub in thoroughly until gel is absorbed, **children under 2 years of age:** consult a doctor.

Inactive Ingredients

aloe barbadensis leaf juice, carbomer, decyl glucoside, purified water, citrus grandis (grapefruit) seed extract, camellia sinensis (green tea) leaf extract, citrus limon (lemon)

peel oil, spiraea ulmaria flower (queen of the prairie) extract, rosa damascena flower water, sodium carbonate, glycerin, hamamelis virginiana (witch hazel) leaf extract, yucca schidigera root extract, phenoxyethanol, caprylyl glycol

Questions or Comments

1-800-225-3963

Drug Facts MDC 61577-1020-4
Active Ingredients: Menthol, USP 6.0%
Purpose: External analgesic
Uses: Temporarily relieves minor aches and pains of muscles and joints associated with: ■ strains ■ bruises ■ sprains
Warnings: For external use only. Do not use on wounds or damaged skin or with a heat source. If pregnant or breastfeeding, consult a healthcare professional before use. When using this product: ■ avoid bandaging tightly ■ avoid contact with eyes ■ Keep out of reach of children

Energized Pain Relief
COOL THERAPY
 Organic Aloe Vera
 Net Wt. 4 oz. (113.4 g)

Drug Facts (continued)
Stop use and ask a doctor if: ■ condition worsens ■ symptoms persist for more than 7 days ■ symptoms clear up and occur again within a few days
Directions: Adults and children 2 years of age and older: ■ apply to affected area not more than 3 to 4 times daily ■ rub in thoroughly until gel is absorbed ■ Children under 2 years of age: consult a doctor
Inactive Ingredients: Aloe Barbadosis Leaf Juice, Camellia Sinensis (Green Tea) Leaf Extract, Caprylyl Glycol, Carbomer, Citrus Grandis (Grapefruit) Seed Extract, Citrus Limon (Lemon) Peel Oil, Dicyl Glucoside, Glycerin, Hamamelis Virginiana (Witch Hazel) Leaf Extract, Phenoxyethanol, Purified Water, Rosa Damascena Flower Water, Sodium Carbonate, Spiraea Ulmaria Flower (Queen of the Prairie) Extract, Yucca Schidigera Root Extract
Questions or Comments? GoodEnergyProducts.com 800-698-ALOE (2563)

DR WOLFES COOL THERAPY

menthol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:61577-1020 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------|
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 0.06 g in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E) | |
| DECYL GLUCOSIDE (UNII: Z17H97EA6Y) | |
| WATER (UNII: 059QF0KO0R) | |
| GRAPEFRUIT SEED OIL (UNII: 598D944HOL) | |
| GREEN TEA LEAF (UNII: W2ZU1RY8B0) | |
| FILIPENDULA ULMARIA FLOWER (UNII: 06L18L32G6) | |
| ROSA CENTIFOLIA FLOWER OIL (UNII: H32V31VMWY) | |
| SODIUM CARBONATE (UNII: 45P3261C7T) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| WITCH HAZEL (UNII: 101I4J0U34) | |
| YUCCA SCHIDIGERA ROOT (UNII: E2H9ET15AT) | |
| LEMON OIL (UNII: I9GRO824LL) | |
| PHENOXYETHANOL (UNII: HIE492Z3Z3T) | |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:61577-1020-4 | 113.4 g in 1 JAR; Type 0: Not a Combination Product | 03/09/2023 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part348 | 03/09/2023 | |

Labeler - SOMBRA COSMETICS INC. (097464309)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------|---------|-----------|---|
| SOMBRA COSMETICS INC. | | 097464309 | manufacture(61577-1020) , label(61577-1020) |

Revised: 3/2023

SOMBRA COSMETICS INC.