

**SORE NO MORE WARM THERAPRY PLUS CBD 2000MG- menthol camphor 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.

Sore No More Warm Therapy Plus CBD 2000mg Natural Pain Relieving Gel

ACTIVE INGREDIENTS

MENTHOL USP 3%, CAMPHOR USP 3%

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

WARNINGS SECTION

FOR EXTERNAL USE ONLY. DO NOT USE ON WOUNDS OR DAMAGED SKIN. **WHEN USING THIS PRODUCTS:** AVOID BANDAGING TIGHTLY, AVOID CONTACT WITH EYES, **KEEP OUT OF REACH OF CHILDREN.**

STOP USE AND ASK DOCTOR IF: CONDITION WORENS, SYMPTONS PERSIST FOR MORE THAN 7 DAYS, 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, water, citrus grandis (grapefruit) seed extract, camellia sinensis (green tea) leaf extract, citrus aurantium dulcis (orange)

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, cannabidiol, capsicum annuum fruit extract,

Question or comments

1-800-225-3963

Drug Facts NDC 61577-7011-5
Active Ingredients:
 Camphor, USP 3.0%
 Menthol, USP 3.0%
Purpose:
 External analgesic
 External analgesic
Uses:
 Temporarily relieves minor aches and pains of muscles and joints associated with: ■ simple backaches ■ arthritis.
Warnings:
 For external use only. Do not use on wounds or damaged skin or with a heat source. If you are 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. ▶

SORE NO MORE **CBD PLUS 2000mg**
 Warm Pain Relief

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 Barbadensis Leaf Juice, Camellia Sinensis (Green Tea) Leaf Extract, Cannabidiol (potency), Caprylyl Glycol, Capsicum Annuum Fruit Extract, Carbomer, Citrus Aurantium Dulcis (Orange) Peel Oil, Citrus Grandis (Grapefruit) Seed Extract, Dicyl Glucoside, Filipendula Ulmaria (Queen of the Prairie) Flower Extract, Glycerin, Hamamelis Virginiana (Witch Hazel) Leaf Extract, Phenoxyethanol, Purified Water, Rosa Damascena Flower Water, Sodium Carbonate, Yucca Schidigera Stem Extract.
Questions or Comments? 1-800-225-3963

THC-FREE

7 63669 03001 e

5831 Office Blvd. NE • Albuquerque, NM 87110 • 800-225-3963

www.SoreNoMorePLUS.com • Made in the USA • Manufactured by Sombra Wellness Products

SORE NO MORE WARM THERAPY PLUS CBD 2000MG

menthol camphor gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:61577-7012 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------|---------------|
| CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET) | CAMPHOR (SYNTHETIC) | 0.03 g in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E) | |
| DECYL GALLATE (UNII: GJW1U497V5) | |
| water (UNII: 059QF0K00R) | |
| CAPSAICIN (UNII: S07O44R1ZM) | |
| GRAPE SEED OIL (UNII: 930MLC8XGG) | |
| GREEN TEA LEAF (UNII: W2ZU1R98B0) | |
| 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) | |

ORANGE PEEL (UNII: T19T76XD44)

CANNABIDIOL (UNII: 19GBJ60SN5)

MENTHOL (UNII: L7T10EIP3A)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:61577-7012-5 | 113.4 g in 1 JAR; Type 0: Not a Combination Product | 05/23/2022 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part348 | 05/23/2022 | |

Labeler - SOMBRA COSMETICS INC. (097464309)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------|---------|-----------|---|
| SOMBRA COSMETICS INC. | | 097464309 | manufacture(61577-7012) , label(61577-7012) |

Revised: 5/2022

SOMBRA COSMETICS INC.