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.

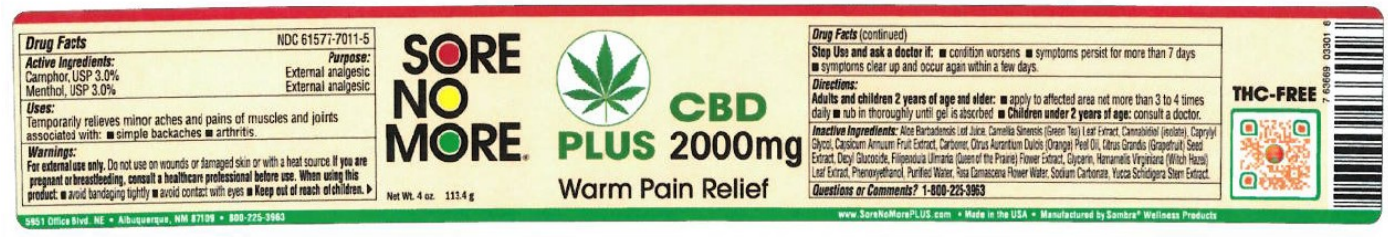
INACTIVE INGREDIENTS

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



SORE NO MORE WARM THERAPRY 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: 059QF0KO0R)	
CAPSAICIN (UNII: S07O44R1ZM)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
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)	

ORANGE PEEL (UNII: TI9T76XD44)	
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.