RE-LEVE- menthol gel
SOMBRA COSMETICS

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.

Ré-LEVE Natural Analgesic Pain Relieving Formula

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

Keep out of reach of children. **For external use only.** Avoid contact with eyes and mucous membranes, wounds or damaged skin. Do not use with heating pads.

Stop uses and ask a doctor if: Conditions worsen, symptoms persist for more than 7 days, symptoms clear up and occur again within a few days.

Directions

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

Inactive Ingredients

aloe barbadensis leaf juice, carbomer, decyl glucoside, water, citrus grandis (grapefruit) seed extract, emu oil, citrus aurantium dulcis (orange) peel oil, glycerin, hamamelis virginiana (witch hazel) leaf extract, yucca schidigera root extract, sodium hydroxymethylglycinate

Questions or Comments? Orders:

Call toll-free: 1-844-303-0037, 155 NE Court St.-152, Prineville, OR, 97754. www.allforu.org. Alcohol-free product made in USA.

RE-LEVE

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61577-3242
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)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
WATER (UNII: 059QF0KO0R)	
CITRUS MAXIMA SEED (UNII: 083X55C543)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
FILIPENDULA ULMARIA FLOWER (UNII: 06L18L32G6)	
ROSA DAMASCENA FLOWER OIL (UNII: 18920M3T13)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
GLYCERIN (UNII: PDC6A3C0OX)	
HAMAMELIS VIRGINIANA LEAF (UNII: T07U1161SV)	
YUCCA SCHIDIGERA ROOT (UNII: E2H9ET15AT)	
LEMON OIL (UNII: I9GRO824LL)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61577-3242-4	113.6 g in 1 JAR; Type 0: Not a Combination Product	03/08/2023	
2	NDC:61577-3242-5	113.6 g in 1 TUBE; Type 0: Not a Combination Product	03/08/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/08/2023	

Labeler - SOMBRA COSMETICS (097464309)

Establishment

Name	Address	ID/FEI	Business Operations
SOMBRA COSMETICS		097464309	manufacture(61577-3242) , label(61577-3242)

Revised: 3/2023 SOMBRA COSMETICS