

**RE-LEVE- menthol gel**  
**SOMBRA COSMETICS INC.**

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**Ré-LEVE Natural Analgesic Pain Relieving Formula**

**Active Ingredients**

Menthol USP 4%

**Purpose**

Purpose  
External Analgesic

**Keep out of reach of children**

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**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.

<b>Drug Facts</b> Menthol, USP 4.0% Uses: Temporarily relieves minor aches and pains of: • Simple backaches • Arthritis • Stains • Bruises • 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 • If symptoms clear up and occur again within a few days	NDC# 61577-3242-4 <b>Purpose</b> External Analgesic	 <p><b>GET YOUR BODY MOVING!™</b></p> <p><b>RE-LEVE™</b></p> <p><b>NATURAL ANALGESIC</b> PAIN RELIEVING FORMULA</p> <p>Net Wt. 4.0 oz. 113.40g</p> <p>Enriched with Emu Oil, Aloe Vera &amp; Orange Peel</p>	<b>Directions:</b> Adult and children 2 years of age and older: • Apply to the affected area not more than 3 to 4 times a day. • Rub until gel is absorbed <b>Children under 2 years of age:</b> consult your doctor. <b>Inactive ingredients:</b> Aloe Barbadensis Leaf Juice, Carbomer, Citrus Aurantium Dulcis (Orange) Peel Oil, Citrus Grandis (Grapefruit) Seed Extract, Decyl Glucoside, Emu Oil, Glycerin, Hamamelis Virginiana (Witch Hazel) Leaf Extract, Sodium Hydroxymethylglycinate, Water, Yucca Schidigera Root Extract <b>Questions? Comments? Orders:</b> Call Toll Free: 1-844-303-0037 155 NE Court St -152, Prineville OR, 97754 www.allforu.org Alcohol Free Product Made in USA	 <p>SPOT UV KNOCKOUT</p> <p>0 140232 49596 0</p>
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## RE-LEVE

menthol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61577-3242
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.06 g in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>CARBOXYPOLYMETHYLENE</b> (UNII: 0A5MM307FC)	
<b>DECYL GLUCOSIDE</b> (UNII: Z17H97EA6Y)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CITRUS MAXIMA SEED</b> (UNII: 083X55C543)	
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)	
<b>FILIPENDULA ULMARIA FLOWER</b> (UNII: 06L18L32G6)	
<b>ROSA DAMASCENA FLOWER OIL</b> (UNII: 18920M3T13)	
<b>SODIUM CARBONATE</b> (UNII: 45P3261C7T)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HAMAMELIS VIRGINIANA LEAF</b> (UNII: T07U1161SV)	
<b>YUCCA SCHIDIGERA ROOT</b> (UNII: E2H9ET15AT)	
<b>LEMON OIL</b> (UNII: I9GRO824LL)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>CAPRYLYL GLYCOL</b> (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	10/05/2016	
2	NDC:61577-	113.6 g in 1 TUBE; Type 0: Not a Combination	10/05/2017	

3242-5

Product

10/05/2017

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M017	10/05/2016	

**Labeler** - SOMBRA COSMETICS INC. (097464309)**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
SOMBRA COSMETICS INC.		097464309	manufacture(61577-3242) , label(61577-3242)

Revised: 5/2025

SOMBRA COSMETICS INC.