

## **TONYS WARM THERAPY- menthol camphor 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.*

-----

## **Dr Tonys Warm Therapy**

### **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: arthritis, simple backaches.

### **warnings**

**For external use only.** Do not use on wounds or damage skin. **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, clear up and 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, capsicum annuum fruit extract

### **Questions or Comments**

1-800-225-3963

SPOT UV VARNISH  
KNOCKOUT

UPC

**TONYO'DONNELL'S**  
G.W. HEALTH PRODUCTS

*Tony's*

# WARM THERAPY

*Natural Pain Relieving Gel*

Net Wt. 3 oz (85g)

*Ireland's Finest*

**G.W. HEALTH PRODUCTS LLC**  
A DIVISION OF O'DONNELL'S RADIANT HEALTH  
29488 MALIBU VIEW COURT ESTATE, AGOURA, CA 91301

## Drug Facts

NDC 61577-3216-5

### 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 pregnant or breastfeeding, ask 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 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, Caprylyl Glycol, Capsicum Annuum Fruit Extract, Carbomer, Citrus Aurantium Dulcis (Orange) Peel Oil, Citrus Grandis (Grapefruit) Seed Extract, Decyl 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.

**TO ORDER CALL: 818-575-7558**  
www.radiantgreens.com • doctony3@netzero.com

**TONYS WARM THERAPY**

menthol camphor gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61577-1400
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.03 g in 1 g
<b>CAMPHOR (SYNTHETIC)</b> (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	0.03 g in 1 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>CARBOMER HOMOPOLYMER TYPE C</b> (UNII: 4Q93RCW27E)	
<b>DECYL GLUCOSIDE</b> (UNII: Z17H97EA6Y)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CAPSAICIN</b> (UNII: S07O44R1ZM)	
<b>GRAPEFRUIT SEED OIL</b> (UNII: 598D944HOL)	
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)	
<b>FILIPENDULA ULMARIA FLOWER</b> (UNII: 06L18L32G6)	
<b>ROSA CENTIFOLIA FLOWER OIL</b> (UNII: H32V31VMWY)	
<b>SODIUM CARBONATE</b> (UNII: 45P3261C7T)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>WITCH HAZEL</b> (UNII: 101I4J0U34)	
<b>YUCCA SCHIDIGERA ROOT</b> (UNII: E2H9ET15AT)	
<b>ORANGE PEEL</b> (UNII: T19T76XD44)	
<b>PHENOXYETHANOL</b> (UNII: H1E492ZZ3T)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	

**Product Characteristics**

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:61577-1400-3	85 g in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	09/13/2021	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/13/2021	

**Labeler** - Sombra Cosmetics (097464309)

## Establishment

Name	Address	ID/FEI	Business Operations
Sombra Cosmetics		097464309	manufacture(61577-1400)

Revised: 9/2021

Sombra Cosmetics