

## **BRAZILIAN HEAT BRAZILIAN HEAT- menthol liquid**

**Oxigenesis, 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.*

-----

### **Drug Facts**

#### **Active Ingredient**

##### **Active Ingredient**

Menthol 7.0%

#### **Inactives**

Alcohol, Dimethyl Sulfone (MSM),  
Eucalyptus Oil, Gelidiella acerosa,  
Hydrogen Peroxide and Chlorine  
Dioxide, Hypnea musciformis,  
Magnesium, Peppermint Oil,  
Sargassum filipendula,  
Sodium, Sorbitol, Water, Zinc

#### **Purpose**

Purpose

External analgesic

#### **Use**

- For the temporary relief of pain and soreness.
- May help distract from pain.
- May provide a cooling sensation.

#### **Warnings**

**Only for external use.**

**Flammable. Keep away from heat or flame.**

- Do not apply to irritated skin or if excessive irritation develops
- Avoid getting into the eyes or mucos membranes.

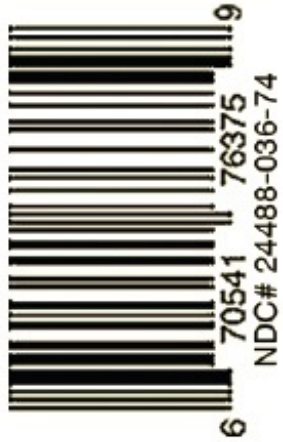
#### **Directions**

Spray a light mist over the affected area up to 6 times daily. Allow to air dry.

Keep out of reach children

**Inactive Ingredients**  
 ASO® Activated Oxygen,  
 LTSM® Zinc, LTSM® Magnesium,  
 Deionized Water, Gellidiela  
 acerosa, Dimethylsulfone  
 (MSM), Sodium PCA, Hypnea  
 musciformis, Sargassum  
 filipendula, Sorbitol,  
 Eucalyptus and  
 Peppermint oils.

**Questions:**  
 Paso Robles, CA 93446 USA  
 805.549.0275  
 www.oxygenesis.com  
 Made in the U.S.A.



**DRUG FACTS**

Active Ingredient	Purpose
Menthol 7.0%	Topical analgesic

**Use:** • For the temporary relief of pain and soreness. • May help cfrom pain. • May provide a cooling sensation.

**Warnings: Only for external use.**

**Flammable. Keep away from heat or flame.**  
 • Do not apply to irritated skin or if excessive irritation develops.  
 • Avoid getting into the eyes or mucos membranes.

**Keep out of the reach of children.**  
 If swallowed, seek medical advice or contact a Poison Control Center immediately.

**Directions:**  
 Spray a light mist over the affected area up to 6 times daily. Allow to air dry

Formulated & Distributed by:  
**OXIGENESIS, INC.**  
 Paso Robles, CA 93446 U.S.A.  
 805.549.0275  
 www.oxygenesis.com  
 LOT FE1828.1 EXP 03/2020

BRAZILIAN HEAT BRAZILIAN HEAT			
menthol liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72136-001
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)		Menthol	70 mg in 1 mL
Inactive Ingredients			
Ingredient Name			Strength
ALCOHOL (UNII: 3K9958V90M)			
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)			
EUCALYPTUS OIL (UNII: 2R04ONI662)			
GELIDIELLA ACEROSA (UNII: T91K54D6M1)			

<b>HYDROGEN PEROXIDE</b> (UNII: BBX060AN9V)
<b>CHLORINE DIOXIDE</b> (UNII: 8061YMS4RM)
<b>HYPNEA MUSCIFORMIS</b> (UNII: W6FF9R1FJV)
<b>MAGNESIUM</b> (UNII: I38ZP9992A)
<b>PEPPERMINT OIL</b> (UNII: AV092KU4JH)
<b>SARGASSUM FILIPENDULA</b> (UNII: 55P66J5H7N)
<b>SODIUM</b> (UNII: 9NEZ333N27)
<b>SORBITOL</b> (UNII: 506T60A25R)
<b>WATER</b> (UNII: 059QF0KO0R)
<b>ZINC</b> (UNII: J41CSQ7QDS)

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72136-001-01	60 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	03/27/2018	

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/27/2018	

**Labeler** - Oxigenesis, Inc (006774725)

**Registrant** - Oxigenesis, Inc (006774725)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Oxigenesis, Inc		006774725	manufacture(72136-001)