

**IOLITE- benzocaine gel**  
**Dharma Research, Inc.**

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**Active Ingredient**

Benzocaine, 20%

**Purpose**

Oral anesthetic

**Uses**

For the temporary relief of pain associated with canker sores and minor dental procedures.

**Warnings**

**Methemoglobinemia warning**

Use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in the blood. This can occur even if you have used this product before.

**Stop use** and seek medical attention if you or a child in your care develops:

- pale, gray, or blue colored skin (cyanosis)
- headache
- rapid heart rate
- shortness of breath
- dizziness or lightheadedness
- fatigue or lack of energy

**Allergy alert Do not use** this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine, or other "-caine" anesthetics.

**Do not use** this product for more than 7 days unless directed by a dentist or a doctor. If sore mouth symptoms do not improve in 7 days; if irritation, pain, or redness persists or worsens; or if swelling, rash, or fever develops, see your dentist or doctor promptly.

**Do not** exceed recommended dosage.

**Keep Out of Reach of Children.** If more than used for pain is accidentally swallowed, get medical help or contact a Poison Control center right away.

**Directions**

- Adults and children 2 years of age and older: Apply to the affected area. Use up to 4 times daily or as directed by a dentist or doctor.
- Children under 12 years of age should be supervised in the use of this product

- Children under 2 years of age: Consult a dentist or doctor.

## Other Information

Store at room temperature 59-86°F (15-30°C). Protect from freezing and heat.

## Inactive Ingredients

FD&C Red #40, FD&C Yellow #5, Flavor, Polyethylene glycol 3350, Polyethylene glycol 400, Saccharine sodium, Tocopheryl acetate, Xylitol

## Iolite

Oral Anesthetic Gel Mango Frappe

with Vitamin E and Xylitol



Gluten Free

1.12 oz (32 g)

Manufactured by Dharma Research, Inc., 5220 NW 72nd Ave, Unit 15, Miami, FL 33166

1-877-833-3725

www.dharmaresearch.com

<p>Manufactured by:</p>  <p>5220 N.W. 72nd Avenue Unit 15, Miami, FL 33166 1-877-833-3725 WWW.DHARMARESEARCH.COM</p>	<p><b>Directions</b></p> <p>• Adults and children 12 years of age and older: Apply to the affected area. Use up to 4 times daily or as directed by dentist or doctor.</p> <p>• Children under 12 years of age should be supervised in the use of the product.</p> <p>• Children under 2 years of age: Consult a dentist or doctor.</p>	<p><b>Other Information</b></p> <p>Store at room temperature 59-86°F (15-30 °C). Protect from freezing and heat.</p>	<p><b>Inactive Ingredients</b></p> <p>FD&amp;C Red #40, FD&amp;C Yellow #5, Flavor, Polyethylene glycol 3350, Polyethylene glycol 400, Saccharine sodium, Tocopheryl acetate, Xylitol.</p>	<p><b>Drug Facts</b></p> <p><b>Active Ingredients</b> Benzocaine, 20%</p> <p><b>Purpose</b> Oral Anesthetic</p> <p><b>Uses</b> For the temporary relief of pain associated with canker sores and minor dental procedures.</p> <p><b>Warnings</b> continued on inside panel</p>	 <p><b>iolite</b> ORAL ANESTHETIC GEL with VITAMIN E and XYLITOL GLUTEN FREE 1.12 oz (32g)</p>	<p>Methemoglobinemia: Use of this product may cause methemoglobinemia, a serious condition that can be treated promptly because it reduces oxygen carried in the blood. This can occur even if you use and seek dental attention if you or a child in your care develops pale, bluish, or ashen (skin cyanosis), headache, rapid heart rate, weakness or dizziness or irritability or lack of energy.</p> <p><b>Warnings</b></p> <p>Do not use this product for more than 7 days unless directed by a dentist. If you experience any of the following main symptoms do not improve in 7 days, or redness, peeling or sores, or a swelling, rash or your dentist or doctor promptly.</p> <p>Do not exceed recommended dosage.</p> <p>Keep out of reach of children. If use is accidentally swallowed, call a Poison Control Center (800) 527-0899.</p>
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<b>IOLITE</b>			
benzocaine gel			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53045-133
<b>Route of Administration</b>	ORAL, DENTAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>	
Benzocaine (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	Benzocaine	6.4 g in 100 g	
<b>Inactive Ingredients</b>			

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
XYLITOL (UNII: VCQ006KQ1E)	

### Product Characteristics

Color		Score	
Shape		Size	
Flavor	MANGO	Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53045-133-30	32 g in 1 BOTTLE; Type 0: Not a Combination Product	07/19/2017	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	07/19/2017	

**Labeler** - Dharma Research, Inc. (078444642)

### Establishment

Name	Address	ID/FEI	Business Operations
Dharma Research, Inc.		078444642	manufacture(53045-133)

Revised: 10/2023

Dharma Research, Inc.