

**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 the 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

Flavor, Polyethylene glycol 3350, Polyethylene glycol 400, Saccharine sodium, Tocopheryl acetate, Xylitol

## Iolite

Oral Anesthetic Cherry Tart Dye Free

With Vitamin E and Xylitol

Gluten Free

1.12 oz (32 g)

Manufactured by: Dharma Research, Inc., 5520 NW 72nd Avenue, Unit 15, Miami, FL, 33166

1-877-833-3725

www.dharmaresearch.com

**Manufactured by:**  
**DHARMA RESEARCH, INC.**  
 5220 N.W. 72 Avenue  
 Unit 15, Miami, FL 33166  
 1-877-833-3725  
 WWW.DHARMARESEARCH.COM

**Directions**  
 Adults and children 12 years of age and older: Apply to the affected area. Reapply every 2 to 4 hours, daily or as directed by a dentist or doctor.  
 Children under 12 years of age should be supervised in the use of the 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**  
 Flavor, Polyethylene glycol 3350, Polyethylene glycol 400, Saccharine sodium, Tocopheryl acetate, Xylitol.

**Drug Facts**  
**Active Ingredients**  
 Benzocaine, 20%  
**Purpose**  
 Oral Anesthetic.  
**Uses**  
 For the temporary relief of pain associated with canker sores and minor dental procedures.  
 Warnings continued on inside panel.

**Warnings**  
 Methemoglobinemia: A rare side effect of this product may cause methemoglobinemia, a serious condition that reduces the amount of oxygen carried in the blood. This can occur even if you use and seek medical attention if you are a child in your care.  
 Side effects: Numbness, tingling, dizziness, or lightheadedness. Stop use if you experience these symptoms.  
 Allergy: Alert to not use the product if you have a history of allergy to local anesthetics such as procaine, benzocaine, or other -caine anesthetics.  
 Do not use this product for more than 7 days unless directed by a dentist. If you experience mouth symptoms or do not improve in 7 days, or if you experience numbness, tingling, or dizziness, or if you experience a rash or other symptoms, stop use and contact a Poison Control Center (1-800-527-0899).

**Keep out of reach of children.** If accidentally swallowed, get medical help or contact a Poison Control Center (1-800-527-0899).

Do not exceed recommended dosage.

<b>IOLITE</b>			
benzocaine gel			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53045-138
<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

## Inactive Ingredients

Ingredient Name	Strength
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	CHERRY	Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53045-138-30	32 g in 1 BOTTLE; Type 0: Not a Combination Product	07/23/2017	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	07/23/2017	

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

## Establishment

Name	Address	ID/FEI	Business Operations
Dharma Research, Inc.		078444642	manufacture(53045-138)

Revised: 10/2023

Dharma Research, Inc.