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

-----

#### **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

**Alergy 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 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 accidentially 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, Flavor, Polyethylene glycol 3350, Polyethylene glycol 400, Saccharine sodium, Tocopheryl acetate, Xylitol

## lolite

Oral Anesthetic Gel Cherry Tart

with Vitamin E and Xylitol

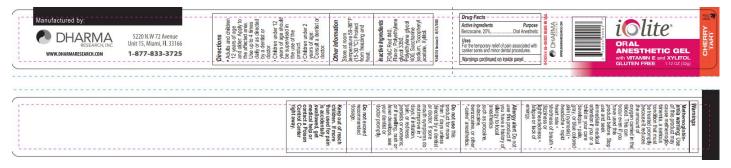
Gluten Free

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



IOLITE								
benzocaine gel								
Product Information								
Product Type	HUMAN OTC DRUG	ltem Code	(Source)	NDC	:53045-131			
Route of Administration	ORAL, DENTAL							
Active Ingredient/Active Moiety								
Ingred	<b>Basis of Stren</b>	gth	Strength					
BENZOCAINE (UNII: U3RSY48JW5)	(BENZOCAINE - UNII:U3RSY	48JW5)	BENZOCAINE		6.4 g in 100 g			
Inactive Ingredients								
	Ingredient Name				Strength			

FD&C RED NO. 40 (UNII: WZB9127XOA)								
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)								
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)								
SACCHARIN SODIUM (UNII: SB8ZUX40TY)								
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)								
XYLITOL (UNII: VCQ006KQ1E)								
Product Chara	acteristics							
Color			Score					
Shape			Size					
Flavor		CHERRY	Imprint	Imprint Code				
Contains								
Contains								
contains								
Contains								
Packaging								
	Pa	ckage Description		Marketing Start Date	Marketing End Date			
Packaging # Item Code		<b>ckage Description</b> TLE; Type 0: Not a Comb	ination	-	-			
Packaging # Item Code 1 NDC:53045-131-	32 g in 1 BOT		ination	Date	-			
Packaging # Item Code 1 NDC:53045-131-	32 g in 1 BOT		ination	Date	-			
Packaging # Item Code 1 NDC:53045-131-	32 g in 1 BOT Product	TLE; Type 0: Not a Comb	ination	Date	-			
Packaging # Item Code 1 NDC:53045-131- 30	32 g in 1 BOT Product	TLE; Type 0: Not a Comb		Date	-			
Packaging # Item Code 1 NDC:53045-131- 30 Marketing Marketing	32 g in 1 BOT Product	TLE; Type 0: Not a Comb tion ntion Number or Mon		Date 07/19/2017 Marketing Start	Date Marketing End			

# Labeler - Dharma Research, Inc. (078444642)

Establishment								
Name	Address	ID/FEI	<b>Business Operations</b>					
Dharma Research, Inc.		078444642	manufacture(53045-131)					

Revised: 10/2023

Dharma Research, Inc.