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 #3, FD&C Blue #1, Flavor, Polyethylene glycol 3350, Polyethylene glycol 400, Saccharine sodium, Tocopheryl acetate, Xylitol, Water

Iolite

Oral Anesthetic Gel Concord Grape

with Vitamin E and Xylitol

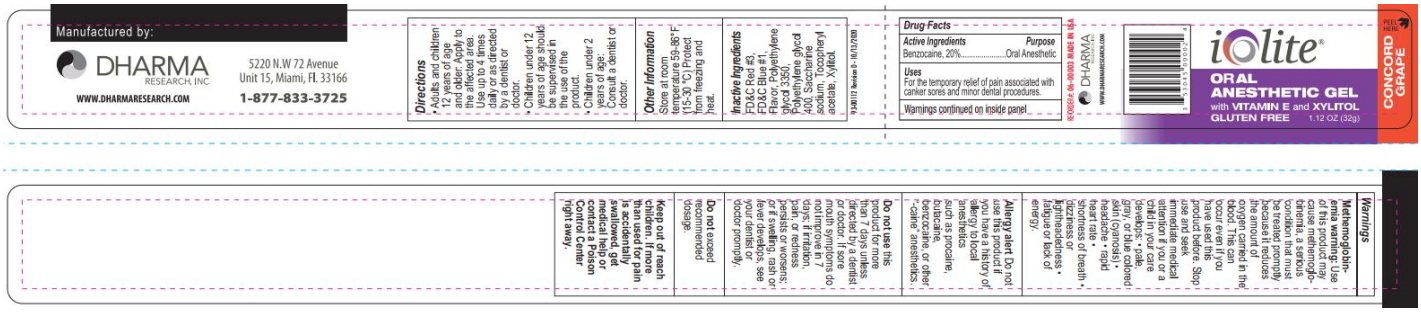
Gluten Free

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	**Item Code (Source)**	NDC:53045-132
Route of Administration	ORAL, DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	6.4 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
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	grape	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53045-132-30	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(53045-132)

Revised: 10/2023 Dharma Research, Inc.