

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

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 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 #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

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

Directions
 • Adults and children 12 years of age and older: Apply to and rub into the area to be treated. Use up to 4 times daily or as directed by dentist or doctor.
 • Children under 12 years of age should be treated in the presence of a parent or caregiver. Use only as directed by dentist or doctor.
 • 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

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

Warnings
 Methemoglobinemia: A serious condition that can cause methemoglobinemia, a serious condition that can be treated promptly because it reduces oxygen carried in the blood. The sun block even if you use and seek medical attention if you or a child in your care develops pale, bluish, or ashy (pale) skin (pallor), headache, rapid heart rate, or dizziness or lightheadedness. Stop use if you experience any of these symptoms.

Allergy Alert Do not use this product if you are allergic 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 do not see improvement in 7 days, or if you experience any of the following, call your dentist or doctor promptly:
 • Swelling, pain, or redness of the mouth
 • Mouth symptoms do not improve in 7 days
 • Pain, or redness, or swelling, or sores in the mouth
 • Rash or hives on your face or body

Do not exceed recommended dosage.

Keep out of reach of children. If this product is accidentally swallowed, call a Poison Control Center (1-800-422-4643).

Keep out of reach of children. If this product is accidentally swallowed, call a Poison Control Center (1-800-422-4643).

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.