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 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 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 Strawberry Shortcake

with Vitamin E and Xylitol

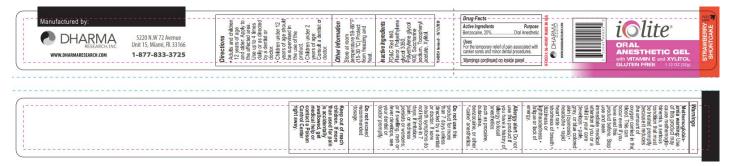
Gluten Free

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:	53045-136		
Route of Administration	ORAL, DENTAL						
Active Ingradient/Active	Mojety						
Active Ingredient/Active Moiety							
Ingredient Name Benzocaine (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)			Basis of Streng Benzocaine		Strength 6.4 g in 100 g		
		0, ••0)	Denzocame		0.4 g in 100 g		
Inactive Ingredients							

Ingredient Name					Strer	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 Characteristics							
Color			Sco	ore			
Shape			Size	e			
Flavor		STRAWBERRY	Imp	orint Code			
Contains							
Packaging							
# Item Code		Package Description		Marketing Start Date	Marketin Date		
	2 g in 1 ł roduct	BOTTLE; Type 0: Not a Combination	0	7/23/2017			
	-	<u> </u>					
Marketing Information							
Marketing Category	Арр	lication Number or Monograp Citation	h	Marketing Start Date	Marketir Dat	-	
OTC Monograph Drug	M022			07/23/2017			

Labeler - Dharma Research, Inc. (078444642)

Establishment								
Name	Address	ID/FEI	Business Operations					
Dharma Research, Inc.		078444642	manufacture(53045-136)					

Revised: 10/2023

Dharma Research, Inc.