

**OPAHL DYE FREE- benzocaine gel**  
**Dharma Research, Inc.**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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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**

**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 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, Water

Opahl 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

NDC 53045-112-30

Manufactured by:  
**DHARMA**  
RESEARCH, INC  
WWW.DHARMARESEARCH.COM

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Unit 15, Miami, FL 33166  
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Re-order: 08-00036  
MADE IN USA

**Opahl**  
DYE FREE  
ORAL ANESTHETIC GEL  
with VITAMIN E and XYLITOL  
GLUTEN FREE 1.12 OZ (32g)

PEEL HERE

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

6.9375"  
**OUTSIDE**

3.5"  
**INSIDE FRONT PANEL**

3.4375"

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## OPAHL DYE FREE

benzocaine gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53045-112
<b>Route of Administration</b>	ORAL, DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	6.4 g in 32 g

### Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
XYLITOL (UNII: VCQ006KQ1E)	
Water (UNII: 059QF0KO0R)	

### Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY (Cherry Tart)	Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53045-112-30	32 g in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	11/02/2013	

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

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

### Establishment

Name	Address	ID/FEI	Business Operations
Dharma Research, Inc.		078444642	manufacture(53045-112)

Revised: 11/2013

Dharma Research, Inc.