

**MARK 3- benzocaine gel**  
**Cargus International, 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 12 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, Saccharin sodium, Tocopheryl acetate, Xylitol

**Distributed by**

Mark 3, 135 North Rt. 9W, Congers, NY, 10920

1-888-732-2913

Mark 3

Oral Anesthetic Gel

Strawberry Dye Free

Gluten Free

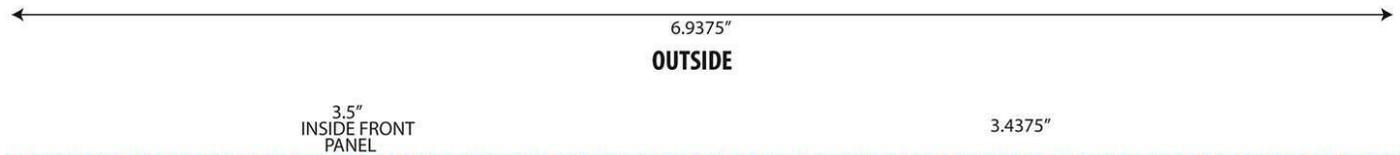
with Vitamin E and Xylitol

NDC 61509-109-32

Net Wt. 1.12 oz. (32 g)

Distributed by Mark 3, 135 North Rt. 9W, Congers, NY 10920

Made in USA



<p><b>Warnings</b>  <b>Allergy alert</b> Do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine, or other "-caine" anesthetics.  <b>Do not use</b> 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.  <b>Do not</b> exceed recommended dosage.  <b>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.</b></p>	<p><b>Directions</b>                  • Adults and children 12 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.  <b>Other Information</b>                  Store at room temperature 59-86° F (15-30° C). Protect from freezing and heat.  <b>Inactive Ingredients</b>                  Flavor, Polyethylene glycol 3350, Polyethylene glycol 400, Saccharine sodium, Tocopheryl acetate, Xylitol.</p>
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<b>MARK 3</b>			
benzocaine gel			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61509-109
<b>Route of Administration</b>	ORAL, DENTAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	6.4 g in 32 g

**Inactive Ingredients**

Ingredient Name	Strength
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	STRAWBERRY	Imprint Code	
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61509-109-32	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	03/03/2014	

**Labeler** - Cargus International, Inc. (096191093)**Establishment**

Name	Address	ID/FEI	Business Operations
Dharma Research, Inc.		078444642	manufacture(61509-109)

Revised: 3/2014

Cargus International, Inc.