

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.

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, Saccharine sodium, Tocopheryl acetate, Xylitol

Distributed by

Mark 3, 135 North Rt. 9W, Congers, NY 10920
1.888.732.2913

Mark 3

Oral Anesthetic Gel

Cherry Dye Free

Gluten Free

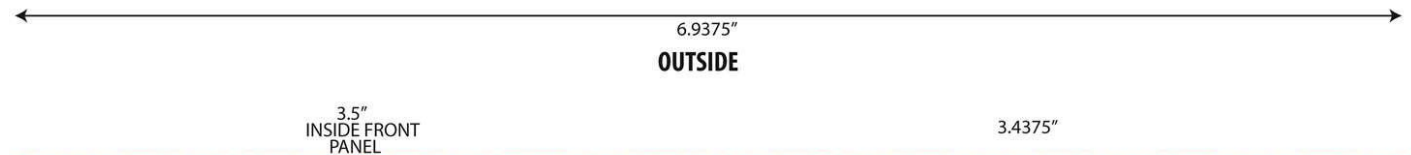
with Vitamin E and Xylitol

NDC 61509-108-32

Net Wt. 1.12 oz. (32 g)

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

Made in USA



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MARK 3 benzocaine gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61509-108
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 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	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61509-108-32	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	03/03/2012	

Labeler - Cargus International, Inc. (096191093)

Establishment

Name	Address	ID/FEI	Business Operations
Dharma Research, Inc.		078444642	manufacture(61509-108)

Revised: 3/2014

Cargus International, Inc.