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

FD&C Red No. 40, 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

Bubble Gum

Gluten Free

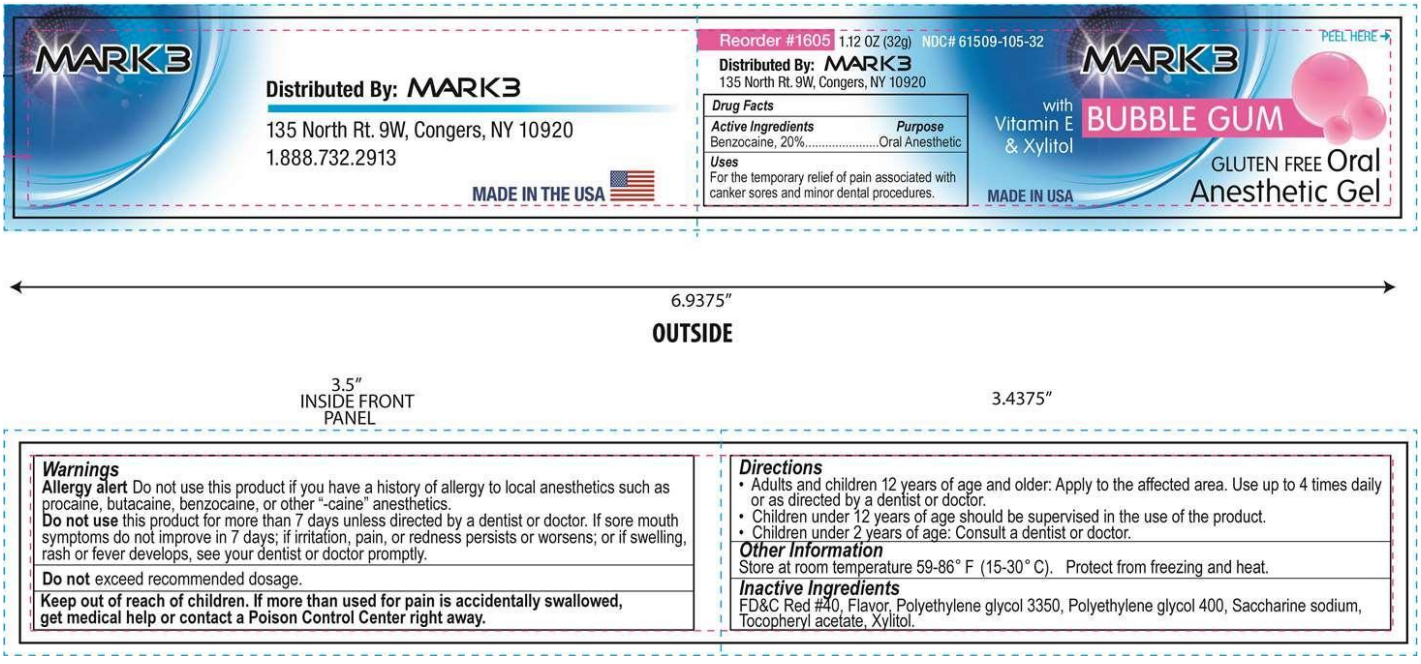
with Vitamin E and Xylitol

NDC 61509-105-32

Net Wt. 1.12 oz. (32 g)

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

Made in USA



MARK 3

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61509-105
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
FD&C RED NO. 40 (UNII: WZB9127XOA)	
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	BUBBLE GUM	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61509-105-32	32 g in 1 BOTTLE; Type 0: Not a Combination Product	03/23/2021	

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(61509-105)