

ALPHA-CAINE TOPICAL ANESTHETIC- benzocaine gel
Dental Technologies, Inc.

Alpha-Caine Drug Facts - Bubble Gum

Active ingredient

Benzocaine 20%

Purpose

Oral Anesthetic

Uses

For the temporary relief of occasional minor irritation and pain, associated with:

- Sore mouth and throat
- Ulcers
- Minor dental procedures
- Needle punctures
- Minor irritation of the mouth and gums caused by dentures or orthodontic appliances

Warnings

For external use only

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 blood. This can occur even if you have used this product before. Stop use and seek immediate 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 if you have a history of allergy to any "caine" anesthetics, such as benzocaine, butacaine, procaine or tetracaine.

Sore throat warning:

If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, see your dentist or doctor promptly.

Do not use

- for teething
- in children under 2 years of age

When using this product

avoid contact with eyes

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact Poison Control Center right away.

Directions

do not exceed recommended dosage.

- **adults and children 2 years of age and older:** apply to affected area. Gargle, swish around in the mouth, or allow to remain in place at least 1 minute and then spit out. Use up to 4 times daily or as directed by dentist or doctor.
- **children under 12 years of age:** should be supervised in the use of the product.
- **children under 2 years of age:** do not use

Other information

Store at 59° to 86° F (15° to 30° C)

Inactive ingredients

Blue 1*, flavor, PEG-8, PEG-75, Red 3*, Red 33*, Red 40*, sodium saccharin, Yellow 10*

*contains one or more of these ingredients.

Questions or comments?

Questions or comments?

1-800-835-0885 or 1-847-677-5500 M-F 8:00 a.m. – 4:30 p.m. CST.

Visit www.dentaltech.com

Principal Display Panel

DENTAL

TECHNOLOGIES

www.dentaltech.com

ALPHA-CAINE

TOPICAL ANESTHETIC GEL

DENTAL TECHNOLOGIES, INC.

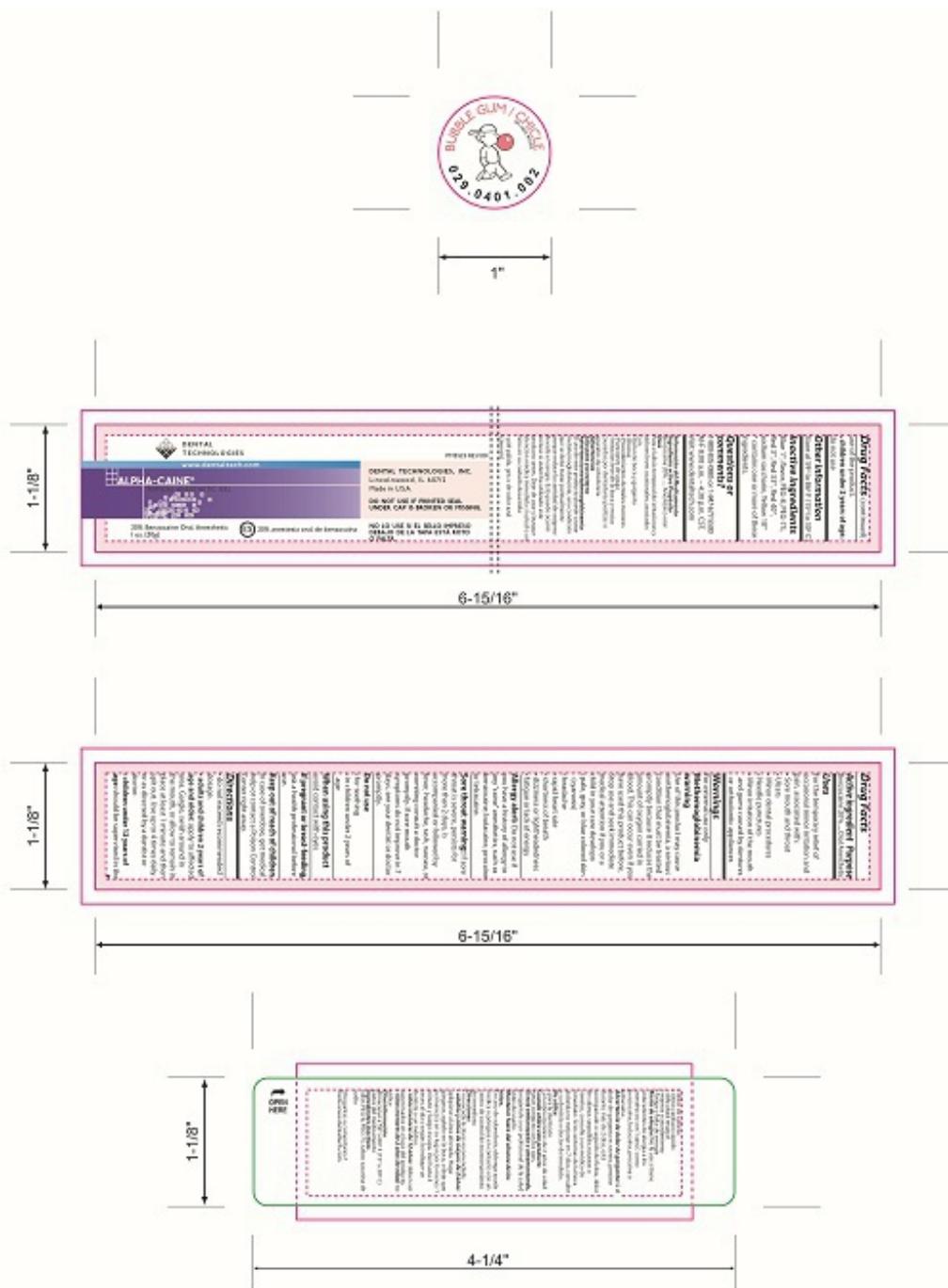
Lincolnwood, IL 60712

Made in U.S.A.

DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING.

20% Benzocaine Oral Anesthetic

1oz. (30g)



ALPHA-CAINE TOPICAL ANESTHETIC

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55346-2904
Route of Administration	PERIODONTAL, DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	200 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BUBBLE GUM (Bubble Gum)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55346-2904-1	30 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/31/1999	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	12/31/1999	

Labeler - Dental Technologies, Inc. (148312838)

Registrant - Dental Technologies, Inc. (148312838)

Establishment

Name	Address	ID/FEI	Business Operations
Dental Technologies, Inc.		148312838	manufacture(55346-2904) , pack(55346-2904) , label(55346-2904)

Revised: 11/2023

Dental Technologies, Inc.