

COMFORTCAINE TOPICAL ANESTHETIC- benzocaine gel
Dental Technologies, 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.

Drug Facts

Active Ingredient

Benzocaine 20%

Purpose

Oral Anesthetic

Uses

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

- canker sores
- ulcers
- minor dental procedures
- needle punctures
- minor injury of the mouth and gums
- minor irritation of the mouth and gums caused by dentures or orthodontic appliances
- sore mouth and throat

Warnings

Do not use if you have a history of allergy to any "caine" anesthetics, such as benzocaine, butacaine, procaine, or tetracaine.

Stop use and ask a doctor if

- Sore mouth symptoms do not improve in 7 days or if irritation, pain, or redness persists or worsens.
- Sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, nausea, rash, swelling, or vomiting.

When using this product

- Avoid contact with eyes

Keep out of reach of children.

If more than used for pain is accidentally swallowed, get medical help or contact a Poison Control Center immediately.

Directions

Do not exceed recommended dosage. Adults and children 2 years of age or older

Apply to the affected area. Allow to remain in place at least 1 minute and then spit out. Use up to 3 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:

Do not use if imprinted seal under cap is broken or missing.

Store at 59° to 86° F (15° to 30° C)

Inactive ingredients :

Flavoring, polyethylene glycol base, sodium saccharin.

Questions or Comments ?

Call 1-800-323-4532 or 1/847-679-3400

M-F: 8:00AM to 5:00PM

Central Time

Bosworth® Company

7227 N. Hamlin Avenue

Skokie, IL 60076

800.323.4352

Principal Display Panel

Bosworth® ComfortCaine™

Topical Anesthetic

NDC 55346-1404-1

Ref 16603

1 oz.(30g.)

Cherry

0510PR725

Drug Facts

Active Ingredient Purpose
Benzocaine 20% Oral Anesthetic

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

- canker sores ■ ulcers
- minor dental procedures
- needle punctures
- minor injury of the mouth and gums
- minor irritation of the mouth and gums caused by dentures or orthodontic appliances
- sore mouth and throat

Warnings
Do not use if you have a history of allergy to any "caine" anesthetics, such as benzocaine, butacaine, procaine, or tetracaine.

Stop use and ask a doctor if

- Sore mouth symptoms do not improve in 7 days or if irritation, pain, or redness persists or worsens.
- Sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, nausea, rash, swelling, or vomiting.

When using this product

- Avoid contact with eyes

Keep out of reach of children. If more than used for pain is accidentally swallowed, get medical help or contact a Poison Control Center immediately.

Directions Do not exceed recommended dosage. Adults and children 2 years of age or older Apply to the affected area. Continued on back

OPEN HERE

Allow to remain in place at least 1 minute and then spit out. Use up to 3 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:
Do not use if imprinted seal under cap is broken or missing. Store at 59° to 86° F (15° to 30° C)

Inactive ingredients:
Flavoring, polyethylene glycol base, sodium saccharin.

Questions or Comments?
Call 1-800-323-4532 or 1/847-679-3400
M-F: 8:00AM to 5:00PM
Central Time

Bosworth ComfortCaine
Topical Anesthetic
NDC 55346-1402-1

1 oz. (30g.)
Cherry
0111PR725

Ref: 16603



OPEN HERE

Bosworth ComfortCaine
Topical Anesthetic
NDC 55346-1402-1

1 oz. (30g.)
Cherry
0510PR725

Ref: 16603

Bosworth Company
2700 West 10th Avenue
Stokes, L. 80074
800.323.4532



OPEN HERE

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55346-1404
Route of Administration	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)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55346-1404-1	30 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	01/01/1997	

Labeler - Dental Technologies, Inc. (148312838)