# 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.

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### **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

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| benzocaine gel             |                      |                    |                |
|----------------------------|----------------------|--------------------|----------------|
| <b>Product Information</b> |                      |                    |                |
| Product Type               | HUMAN OTC DRUG LABEL | Item Code (Source) | NDC:55346-1404 |

DEA Schedule

| Active Ingredient/Active Moiety |                   |               |  |
|---------------------------------|-------------------|---------------|--|
| Ingredient Name                 | Basis of Strength | Strength      |  |
| Benzocaine (BENZOCAINE)         | Benzocaine        | 200 mg in 1 g |  |

DENTAL

| Inactive Ingredients     |          |
|--------------------------|----------|
| Ingredient Name          | Strength |
| Polyethylene Glycol 400  |          |
| Polyethylene Glycol 3350 |          |
| SACCHARIN SO DIUM        |          |
| SILICON DIO XIDE         |          |
| FD&C RED NO. 3           |          |

| Product Characteristics |                 |              |  |
|-------------------------|-----------------|--------------|--|
| Color                   |                 | Score        |  |
| Shape                   |                 | Size         |  |
| Flavor                  | CHERRY (Cherry) | Imprint Code |  |
| Contains                |                 |              |  |

| Packaging          |                     |                             |                    |
|--------------------|---------------------|-----------------------------|--------------------|
| # Item Code        | Package Description | <b>Marketing Start Date</b> | 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                                  | 0 1/0 1/19 9 7       |                    |
|                         |  |                      |                    |

## Labeler - Dental Technologies, Inc. (148312838)

Route of Administration

Revised: 11/2012 Dental Technologies, Inc.