

## CVS ORAL ANESTHETIC - benzocaine liquid

### CVS Pharmacy

*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

#### Purpose

Benzocaine, 20%.....Oral Anesthetic

### Uses

- temporary relieves pain associated with the following mouth and gum irritations:
- toothache - canker sores - sore gums - braces - dentures
- minor dental procedures

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

### Uses

- temporary relieves pain associated with the following mouth and gum irritations:
- toothache - canker sores - sore gums - braces - dentures
- 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.

### When using this product

- avoid contact with eyes
- do not exceed recommended dosage
- do not use for more than 7 days unless directed by a doctor/dentist

### Stop use and ask a dentist or a doctor if

- sore mouth symptoms do not improve in 7 days
- swelling, rash or fever develops
- irritation, pain or redness persists or worsens

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

**Directions**

- Adults and children 2 years of age and older: apply to the affected area
- wipe liquid on with cotton, or cotton swab, or fingertip
- apply up to 4 times daily or as recommended by a doctor/dentist
  
- Children under 12 years of age: adult supervision should be given in the use of this product
  
- children under 2 years of age: consult a dentist or doctor

**Inactive Ingredients**

benzyl alcohol, D and C Yellow no 10, FD and C Blue no 1, FD and C Red no 40, flavor, methylparaben, polyethylene glycol, propylene glycol, saccharin



# Maximum Strength ORAL ANESTHETIC LIQUID

PAIN RELIEVING LIQUID

### Drug Facts

**Active Ingredient**      **Purpose**  
Benzocaine, 20%.....Oral Anesthetic

**Uses:** temporarily relieves pain associated with the following mouth and gum irritations:  
■ toothache      ■ canker sores  
■ sore gums      ■ braces      ■ dentures  
■ 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.

**When using this product**  
■ avoid contact with eyes  
■ do not exceed recommended dosage  
■ do not use for more than 7 days unless directed by a doctor/dentist

**Stop use and ask a dentist or a doctor if**  
■ sore mouth symptoms do not improve in 7 days  
■ swelling, rash or fever develops  
■ irritation, pain or redness persists or worsens

### Drug Facts (Continued)

**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 2 years of age and older: apply to affected area  
■ wipe liquid on with cotton, or cotton swab, or fingertip  
■ apply up to 4 times daily or as directed by a doctor/dentist  
■ children under 12 years of age: adult supervision should be given in the use of the product  
■ children under 2 years of age: consult a dentist or doctor

**Other information:** store at 20-25°C (68-77°F)

**Inactive ingredients**  
benzyl alcohol, D&C yellow no.10, FD&C Blue no.1, FD&C Red no. 40, flavor, methylparaben, polyethylene glycol, propylene glycol, saccharin

**TAMPER-EVIDENT:** Do not use if cap seal is broken or missing.



Distributed by: CVS Pharmacy, Inc.  
Woonsocket, RI 02895  
© 2007 CVS/pharmacy  
www.cvs.com

\*This product is not manufactured or distributed by WHITEHALL LABORATORIES, INC., owner of the registered trademark Ambesol®.

ORAL ANESTHETIC LIQUID  
Maximum Strength  
PAIN RELIEVING LIQUID  
Instant toothache pain relief  
1 FL OZ (30 mL)

CVS pharmacy  
Compare to the active ingredient in Ambesol®\*

ORAL ANESTHETIC LIQUID  
Maximum Strength  
PAIN RELIEVING LIQUID  
Instant toothache pain relief  
1 FL OZ (30 mL)

CVS pharmacy  
Compare to the active ingredient in Ambesol®\*

BX004CVS-01  
Rev 04/10

TAMPER-EVIDENT: Do not use if cap seal is broken.



## CVS ORAL ANESTHETIC

benzocaine liquid

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-186
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SPEARMINT OIL (UNII: C3M81465G5)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
METHYL PARABEN (UNII: A218C7H9T)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SACCHARIN (UNII: FST467XS7D)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-186-51	1 in 1 CARTON		
1		30 mL in 1 TUBE, WITH APPLICATOR		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part356	07/08/2010	

**Labeler** - CVS Pharmacy (062312574)

**Registrant** - Pharma Pac, LLC (140807475)

## Establishment

Name	Address	ID/FEI	Business Operations
Pharma Pac, LLC		140807475	manufacture

Revised: 7/2010

CVS Pharmacy