

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

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Drug Facts (Continued)

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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.



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



Compare to the active ingredient in Ambesol®*



BX004CVS-01
 Rev 04/10

Compare to the active ingredient in Ambesol®*



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

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