

CVS PHARMACY MAXIMUM STRENGTH- benzocaine gel, dentifrice
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.

5820329 CVS Max Str Oral Anesthetic Gel

Active ingredient

Benzocaine 20%

Purpose

Oral anesthetic

Use

temporarily relieves pain associated with mouth and gum irritations

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

Stop use and ask a dentist or doctor if

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

When using this product

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

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

- to open tube, cut tip of tube on score mark.
- adults and children 2 years of age and older: apply to affected area up to 4 times daily or as directed by dentist/doctor.
- 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 doctor / dentist.
- for denture irritation apply a thin layer to the affected area; do not reinsert dental

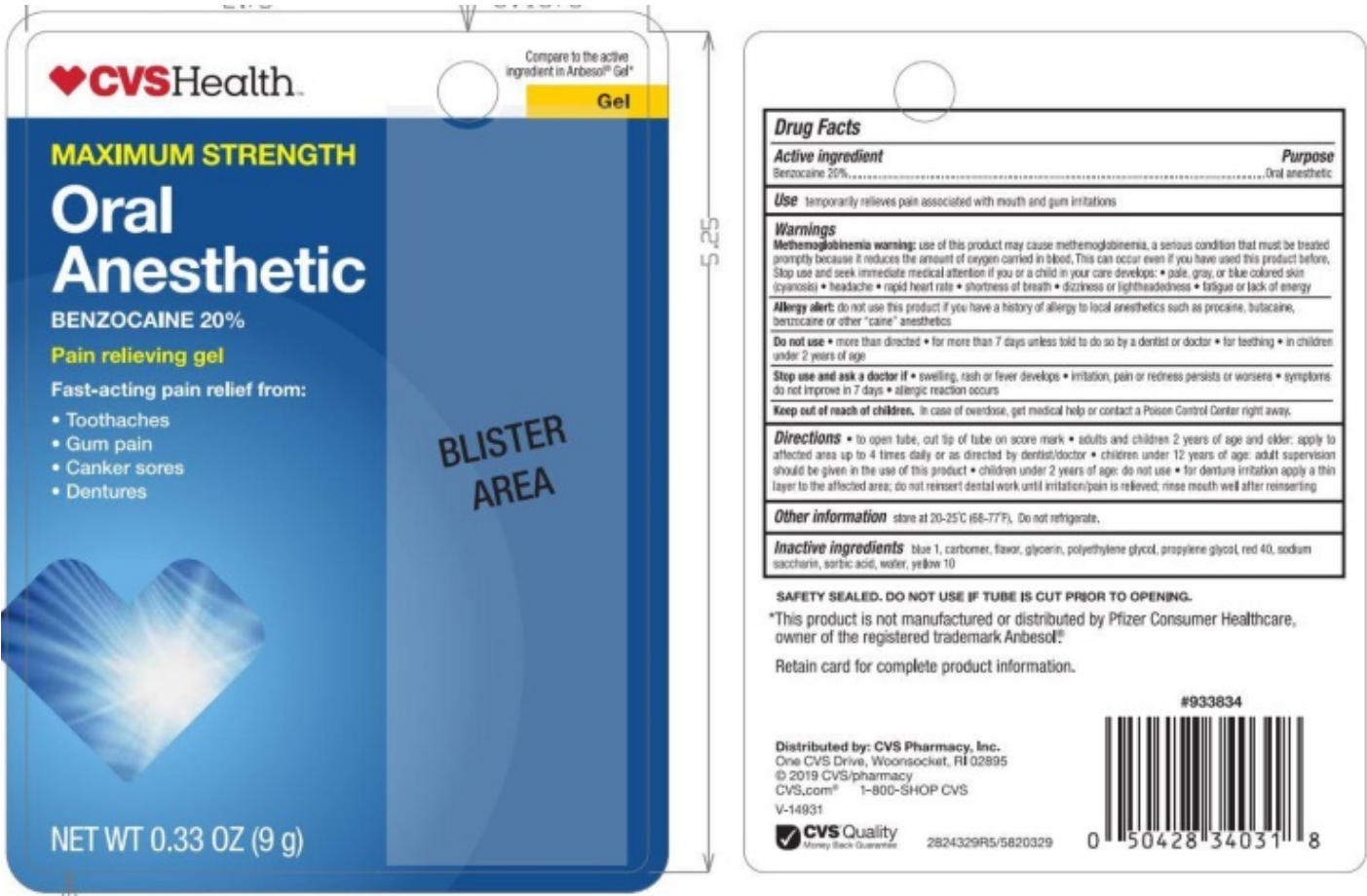
work until irritation/pain is relieved; rinse mouth well after reinserting

Other Information

Store at 20-25C (68-77F). Do not refrigerate

Inactive ingredients

Blue 1, Carbomer, Flavor, Glycerin, Polyethylene Glycol, Propylene Glycol, Red 40, Sodium Saccharin, Sorbic Acid, Water, Yellow 10



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benzocaine gel, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-582
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)		BENZOCAINE	20 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBIC ACID (UNII: X045WJ989B)	
GLYCERIN (UNII: PDC6A3C0OX)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT (Characteristic Mint)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-582-09	1 in 1 CARTON	01/20/2011	
1		9 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	01/20/2011	

Labeler - CVS Pharmacy (062312574)

Registrant - Lornamead (080046418)

Establishment

Name	Address	ID/FEI	Business Operations
Lornamead Inc.		080046418	manufacture(59779-582)