

CVS MAXIMUM STRENGTH- benzocaine paste, 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.

5820321 CVS Max Str Oral Pain Reliever Paste

Active ingredient

Benzocaine 20%

Purpose

Oral pain reliever

Use

for the temporary relief of pain due to

- canker sores
- cold sores
- fever blisters
- minor irritation of the mouth and gums caused by dentures or orthodontic appliances

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 the eyes
- do not use more than directed
- do not use for more than 7 days unless directed by a dentist or doctor.

Stop use and ask 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. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- cut open tip of tube on scoremark
- **adults and children 2 years of age and older:** apply to the affected area up to 4

times daily or as directed by a dentist or doctor. Children under 12 years of age should be supervised in the use of this product.

- **children under 2 years of age:** ask a dentist or doctor.
- 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

Do not use if tip is cut prior to opening. This preparation is intended for use in cases of toothache, only as a temporary expedient until a dentist can be consulted. Do not use continuously. This formula will stay in place for extended duration of relief.

Inactive ingredients

Cellulose Gum, Gelatin, Menthol, Methyl Salicylate, Pectin, Petrolatum, Polyethylene Glycol, Sodium Saccharin.



CVS MAXIMUM STRENGTH			
benzocaine paste, dentifrice			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-123
Route of Administration	TOPICAL		

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
MENTHOL (UNII: L7T10EIP3A)	
PETROLATUM (UNII: 4T6H12BN9U)	
GELATIN (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
SACCHARIN (UNII: FST467XS7D)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
PECTIN (UNII: 89NA02M4RX)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	WMNTERGREEN (L Menthol)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-123-19	1 in 1 CARTON	01/20/2011	
1		12 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 final	part348	01/20/2011	

Labeler - CVS Pharmacy (062312574)**Registrant** - Lornamead Inc. (080046418)**Establishment**

Name	Address	ID/FEI	Business Operations
Lornamead Inc.		080046418	manufacture(59779-123)

