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.

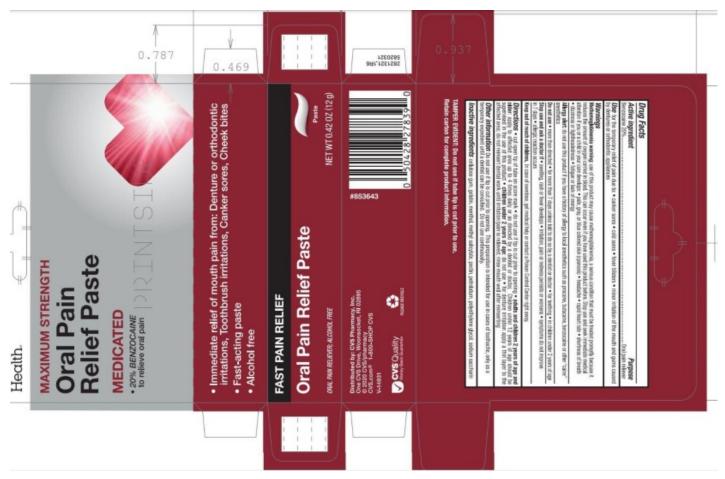
- children under 2 years of age: ask a dentist or doctor.
- for denture irritation apply a thin layer to the affected area; do not reinsert dental work until irritation/pain is relieved; rinse mouth well after reinserting

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 tempory 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	WNTERGREEN (L Menthol)	Imprint Code	
Contains			

P	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)	

Revised: 1/2023 CVS Pharmacy