

TOOTHACHE AND GUM RELIEF- benzocaine, menthol 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.

5820375 CVS Toothache & Gum Relief Liquid

Drug Facts

Active ingredients

Benzocaine 20%

Menthol 0.1%

Purpose

Oral pain reliever

Oral pain reliever

Uses

for the temporary relief of pain due to

- canker sores
- minor injury of the mouth and gums
- minor irritation of the mouth and gums caused by dentures

Warnings

Methemoglobinemia warning: use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. This can occur even if you have used this product before. Stop use and seek immediate medical attention if you or a child in your care develops:

- pale, gray or blue colored skin (cyanosis)
- headache
- rapid heart rate
- shortness of breath
- dizziness or lightheadedness
- fatigue or lack of energy

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

Do not use

- more than directed
- for more than 7 days unless told to do so by a dentist or doctor
- for teething
- in children under 2 years of age

Stop use and ask a doctor if

- swelling, rash or fever develops

- irritation, pain or redness persists or worsens
- symptoms do not improve in 7 days
- allergic reaction occurs

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- do not use if package has been opened
- **adults and children 2 years of age and older:** using applicator tip, apply to the cavity and around the gum surrounding the teeth. Use up to 4 times daily or as directed by a dentist or doctor. Children 12 years of age should be supervised in the use of this product
- **children under 2 years of age:** do not use

Other information 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.

Inactive ingredients alcohol, flavor, polyethylene glycol, red 40, sodium saccharin, water, yellow 5

TAMPER-EVIDENT: Carton is sealed for your protection.

Retain carton for complete product information.

Distributed by: CVS Pharmacy, Inc.

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CVS.com 1-800-SHOP-CVS

Made in Canada

CVS Health™

SEVERE PAIN RELIEF

Toothache & Gum Relief Liquid

ORAL PAIN RELIEVER

DOUBLE MEDICATED

- 20% BENZOCAINE to relieve oral pain
- MENTHOL to soothe

0.5 FL OZ (14.7 mL)



TOOTHACHE AND GUM RELIEF

benzocaine, menthol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-353
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 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.1 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
WATER (UNII: 059QF0KO0R)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
ALCOHOL (UNII: 3K9958V90M)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Product Characteristics

Color	orange (Red orange)	Score	
Shape		Size	
Flavor	FRUIT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-353-29	1 in 1 CARTON	02/07/2019	
1		14.7 mL in 1 BOTTLE, WTH APPLICATOR; 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	02/07/2019	

Labeler - CVS Pharmacy (062312574)

Registrant - Lornamead (080046418)

Establishment

Name	Address	ID/FEI	Business Operations
Lornamead		080046418	manufacture(69842-353)