

## **CVS TOOTH AND GUM PAIN RELIEF CUSHIONS- benzocaine strip**

**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.*

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### **CVS Tooth & Gum Pain Relief Cushions**

#### ***Drug Facts***

#### ***Active ingredient***

Benzocaine 10%

#### ***Purpose***

Oral Pain Reliever

#### ***Use***

for the temporary relief of pain due to toothaches

#### ***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***

- Carefully remove gel cushion from blister. Gently mold with fingers until soft. Apply to affected tooth/gum area and gently press for 5-10 seconds to mold for a comfortable fit. Gel cushion will stay in place and dissolve slowly in mouth.

- **Adults and children 12 years of age and older:** use up to 3 times daily or as directed by dentist or doctor.
- Children under 12 years of age: ask a dentist or doctor
- **Children under 2 years of age:** do not use

***Other information***

Do not use if blister card is broken. 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. These toothache cushions are designed to completely dissolve in place.

Store at room temperature 15-30°C (59-86°F)

***Inactive ingredients***

Cellulose Gum, Flavor, Menthol, Polyethylene Glycol

**Distributed by: CVS Pharmacy, Inc.**

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Made in U.S.A.

CVS Health™

Moldable Gel Cushions

Medicated

**Tooth & Gum Pain Relief Cushions**

BENZOCAINE 10%, ORAL PAIN RELIEVER

For Immediate Pain Relief

- Soothes & comforts
- Long lasting - stays in place twice as long as the leading gel\*
- Great for use with braces

8 GEL CUSHIONS, 0.5 g EACH



\*Based on lab dissolution study.

CVS TOOTH AND GUM PAIN RELIEF CUSHIONS			
benzocaine strip			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-381
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
BENZOCAINE (UNII: U3RS Y48JW5) (BENZOCAINE - UNII:U3RS Y48JW5)		BENZOCAINE	10 g in 100 g

**Inactive Ingredients**

Ingredient Name	Strength
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
MENTHOL (UNII: L7T10EIP3A)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-381-09	8 in 1 CARTON	02/08/2019	
1		0.5 g in 1 BLISTER PACK; 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	02/08/2019	

**Labeler** - CVS Pharmacy (062312574)**Registrant** - Lornamead Inc. (078584069)**Establishment**

Name	Address	ID/FEI	Business Operations
Lornamead Inc.		078584069	manufacture(69842-381)

Revised: 2/2019

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