

## **MOUTH SORE RELIEF PROFESSIONAL STRENGTH- benzocaine 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.*

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### **CVS Mouth Sore Relief**

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

Benzocaine 20% (w/w)

#### ***Purpose***

Oral Anesthetic/Analgesic

#### ***Uses***

for the temporary relief of pain due to canker sores, minor irritation of the mouth and gums caused by dentures or orthodontic appliances, or minor injury of the mouth or gums

For oral use only

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

If sore mouth symptoms do not improve in 7 days; if irritation, pain or redness persists or worsens; or if swelling, rash or fever develops, see your doctor or dentist promptly. Do not exceed recommended dosage.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

#### ***Directions***

- to assure formation of long-lasting film coating, dry affected area and apply medication undiluted with applicator
- allow a few seconds for coating to form
- use 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:** consult a dentist or doctor

#### ***Other Information***

- do not use if package has been opened
- store at 20-25°C (68-77°F)
- close cap tightly after use to avoid evaporation
- avoid contact with eyes
- avoid contact with clothing and household/furniture surfaces to prevent possible staining
- this is a personal care item, and should be used by one individual only

## Inactive ingredients

Benzyl Alcohol, Cetylpyridinium Chloride, Compound Benzoin Tincture, Dimethyl Isosorbide, Ethylcellulose, Flavor, Octylacrylamide/acrylates/butylaminoethyl/methacrylate Copolymer, Oleth-10, PEG-6, Propylene Glycol, Ricinus Communis (Castor) Seed Oil, SD Alcohol 38B, Sucralose, Tannic Acid.



## MOUTH SORE RELIEF PROFESSIONAL STRENGTH

benzocaine liquid

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-830
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	200 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
ETHYLCELLULOSES (UNII: 7Z8S9VYZ4B)	
TANNIC ACID (UNII: 28F9E0DJY6)	
CETYLPIRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

<b>OLETH-10</b> (UNII: JD797EF70J)	
<b>DIMETHYL ISOSORBIDE</b> (UNII: SA6A6V432S)	
<b>RICINUS COMMUNIS SEED</b> (UNII: 7EK4SFN1TX)	
<b>POLYETHYLENE GLYCOL 300</b> (UNII: 5655G9Y8AQ)	
<b>BENZOIN, (+/-)</b> (UNII: L7J6A1NE81)	

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT (Mint Flavor #25797)	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-830-38	1 in 1 BLISTER PACK	04/19/2011	
1		14.7 g in 1 BOTTLE, WITH 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	10/01/2009	

**Labeler** - CVS Pharmacy (062312574)

### Establishment

Name	Address	ID/FEI	Business Operations
CSR Cosmetic Solutions		243501959	manufacture(59779-830) , pack(59779-830)

Revised: 9/2019

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