

CVS 2X LIQ (CSR)- benzocaine liquid
CSR Cosmetic Solutions

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.

5820353 CVS 2x Liq (CSR)

Benzocaine

Menthol

Oral pain reliever

Oral pain reliever

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

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.

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 tooth. 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: do not use

this preparation is intended for use in cases of toothache, only as a temporary expedient until a dentist can be consulted. Do not use continually.

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



CVS 2X LIQ (CSR)

benzocaine liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49354-353
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	0.1 mg in 100 mL

BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)

BENZOCAINE

20 mg
in 100 mL

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
ALCOHOL (UNII: 3K9958V90M)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	red (Red/Orange)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49354-353-39	1 in 1 CARTON	09/02/2021	
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	09/02/2021	

Labeler - CSR Cosmetic Solutions (243501959)

Registrant - Lornamead (080046418)

Establishment

Name	Address	ID/FEI	Business Operations
CSR Cosmetic Solutions		243501959	manufacture(49354-353) , pack(49354-353)