

DG 3X MEDICATED TOOTHACHE AND GUM GEL- benzocaine gel
Dollar General

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.

5820618 DG 3x Med Gel

Benzocaine 20%

Menthol 0.26%

Zinc chloride 0.15%

Oral pain reliever

Oral pain reliever

Oral astringent

for the temporary relief of oral pain due to minor irritation or injury of the mouth and gums

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

cut open tip of tube on score mark * adults and children 2 years of age and older: apply a small amount of product 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 under 12 years of age should be supervised in the use of this product * children under 2 years of age: do not use

do not use if tip is cut prior to opening * 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 * this formula will stay in place for extended duration of relief * avoid using toothpaste or drinking soft drinks or fruit juices for at least one hour after applying * retain carton for complete product information

ammonium glycyrrhizate, flavor, PEG-8, PEG-75, sodium saccharin, sorbic acid

Active ingredients

Active ingredients	Purpose
Benzocaine 20%	Oral pain reliever
Menthol 0.26%	Oral pain reliever
Zinc chloride 0.15%	Oral astringent

Use • for the temporary relief of oral pain due to minor irritation or injury of the mouth and gums. **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. **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:** • cut open tip of tube on score mark • **adults and children 2 years of age and older:** apply a small amount of product 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 under 12 years of age should be supervised in the use of this product • **children under 2 years of age:** do not use. **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 temporary expedient until a dentist can be consulted • do not use continuously • this formula will stay in place for extended duration of relief • avoid using toothpaste or drinking soft drinks or fruit juices for at least one hour after applying • retain carton for complete product information. 1821618R1

DISTRIBUTED BY OLD EAST MAIN CO., 100 MISSION RIDGE, GOODLETTSVILLE, TN 37072

DG 3X MEDICATED TOOTHACHE ADN GUM GEL

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-816
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	20 g in 100 g
ZINC CHLORIDE (UNII: 86Q357L16B) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	0.15 g in 100 g
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	0.26 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBIC ACID (UNII: X045VJ989B)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	

Product Characteristics

Color	white (Cloudy White to Yellow)	Score	
Shape		Size	
Flavor	MINT	Imprint Code	

Contains**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-816-69	1 in 1 CARTON	10/28/2020	
1		9.4 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 not final	part356	10/28/2020	

Labeler - Dollar General (068331990)**Registrant** - Lornamead (080046418)**Establishment**

Name	Address	ID/FEI	Business Operations
Lornamead		080046418	manufacture(55910-816) , pack(55910-816)

Revised: 1/2023

Dollar General