

4X MEDICATED TOOTHACHE AND GUM GEL- benzocaine gel CVS

5820602 4x Medicated Instant Pain Relief Gel

Benzalkonium chloride 0.13% . . . Oral antiseptic

Benzocaine 20% . . . Oral pain reliever

Menthol 0.5% . . . Oral pain reliever

Zinc chloride 0.15% . . . Oral astringent

Use

for the temporary relief of pain due to toothaches * to help protect against infection of minor oral irritation

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

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 least one hour after applying

ammonium glycyrrhizate, blue 1, flavor, PEG-8, PEG-75, sodium saccharin, sorbic acid

NDC 69842-642-29



4x Medicated
INSTANT PAIN RELIEF
For Toothache & Gum
Oral Antiseptic/Pain Reliever/Astringent

**Compare to Orajel™ 4X Medicated
For Toothache & Gum***

4x Medicated
INSTANT PAIN RELIEF
For Toothache & Gum
Oral Antiseptic/Pain Reliever/Astringent

NET WT 0.25 OZ (7 g)

Long-Lasting, Targeted Pain Relief†
Relieves Throbbing Pain
Helps Prevent Infection &
Kills Harmful Bacteria



Gel

NET WT 0.25 OZ (7 g)

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UPC# 050428000427

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5820602

*This product is not manufactured or distributed by Church & Dwight Co., Inc., makers of Orajel™
4X Medicated For Toothache & Gum. †Up to 2 hours.
Retain carton for complete product information.
TAMPER-EVIDENT: Do not use if tube tip is cut prior to use

Drug Facts

Active ingredients
Benzalkonium chloride 0.13%
Menthol 0.5%
Benzocaine 20%
Zinc chloride 0.15%
Oral antiseptic
Oral pain reliever
Oral pain reliever
Oral antiseptic

Purpose
Oral antiseptic
Oral pain reliever
Oral pain reliever

Uses • for the temporary relief of pain due to toothaches • to help protect against infection of minor oral irritation

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, butalbital, benzocaine or other "caine" anesthetics

Do not use • more than directed • for more than 7 days unless directed by a dentist or doctor • for teething in children under 2 years of age

Stop use and ask 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 or allergic reaction, 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 between 2 and 12 years of age: ask a doctor before use. 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 tooth paste or drinking soft drinks or fruit juices for at least one hour after applying

Inactive ingredients ammonium glycyrrhizate, blue 1, flavor, PEG-8, PEG-75, sodium saccharin, sorbic acid

4X MEDICATED TOOTHACHE AND GUM GEL

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-642
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	20 g in 100 g
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	0.5 g in 100 g
ZINC CHLORIDE (UNII: 86Q357L16B) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	0.15 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
SORBIC ACID (UNII: X045WJ989B)	

Product Characteristics

Color	blue	Score	
Shape		Size	
Flavor	WINTERGREEN	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-642-29	1 in 1 CARTON	06/05/2020	
1		7.1 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 Drug	M022	06/05/2020	

Labeler - CVS (062312574)

Registrant - Lornamead Products (119559733)

Establishment

Name	Address	ID/FEI	Business Operations
Lornamead Products		119559733	manufacture(69842-642) , pack(69842-642)

Revised: 11/2025

CVS