4X MEDICATED TOOTHACHE AND GUM GEL- benzocaine gel American Sales

5820624 Ahold CareOne 4x Med 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

Methemoglobinema warning: use of this product may cause methemoglobinemia, a serious condition that must be treated promptly becuase 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 imporve 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 * dults and children 2 years of age and older: apply a small amount of product to the cavity and around teh 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

Compare to Orajel™ 4X Medicated for Toothache & Gum Gel* CARE**ONE**® **4X MEDICATED Toothache & Gum Relief Gel** 20% Benzocaine to relieve oral pain Kills harmful bacteria Astringent to help prevent infection Cools gum & relieves irritation CARE**ONE**® **4X MEDICATED Toothache & Gum Relief Gel** Oral pain reliever/astringent/antiseptic Benzalkonium chloride • Benzocaine • Menthol • Zinc Chloride **NET WT 0.25 OZ (7g)** DISTRIBUTED BY: ADUSA DISTRIBUTION, LLC SALISBURY, NC 28147 For product questions or concerns, contact us at 1-833-992-3872 Quality guaranteed or your money back. Retain carton for complete product information TAMPER-EVIDENT: Do not use if tube tip is cut prior to use *This product is not manufactured or distributed by Church & Dwight Co., Inc., the owner of the registered trademark Orajel^{rm}. INACTIVE INGIVECTION SIMMONIUM glycymhizate, blue 1, flavor, PEG-8, PEG-75, sodium saccharin, sorbic acid will stay in place for extended duration of relief • avoid using toothpaste or drinking soft drinks or fruit juices for at pooguscue' only as a temporary expedient until a dentist can be consulted . do not use continuously . this formula Other information • do not use if tip is cut prior to opening • this preparation is intended for use in cases of 2 years of age; do not use a derdist or doctor • children under 12 years of age should be supervised in the use of this product • children under amount of product to the cavity and around the gum surrounding the teeth. Use up to 4 times daily or as directed by DILECTIONS • cut open tip of tube on score mark • adults and children 2 years of age and older: apply a small

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skimbroms do not improve in 7 days • allergic reaction occurs

Marthol 0.5% Oral pain reliever Oral pain due to toothaches • to help protect against infection of minor oral irritation Marmings Marmings Forested promptly because it reduces the amount of oxygen carried in blood. This can occur even if you have each 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) • headsche • rapid heart rate • shortness of breath • disziness or ghtheady alert: do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, encoraine or other "caine" anesthetics	io not use • more than directed • for more than 7 days unless told to do so by a dentist or doctor • for teet In children under 2 years of age
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Neverlever %8.0 lothref	926 • for the temporary relief of pain due to tootbraches • to help protect against infection of minor oral irritati
Active ingredients (513%) (517	

4X MEDICATED TOOTHACHE AND GUM GEL

benzocaine gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:41520-627

Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZ ALKONIUM 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)			

Color Score

Shape		Size
Flavor	WNTERGREEN	Imprint Code
Contains		

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-627- 09	1 in 1 CARTON	11/20/2023	
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	M017	11/20/2023	

Labeler - American Sales (809183973)

Registrant - Lornamead (080046418)

Establishment				
Name	Address	ID/FEI	Business Operations	
Lornamead		080046418	pack(41520-627) , manufacture(41520-627)	

Revised: 11/2023 American Sales