4X MEDICATED TOOTHACHE AND GUM GEL- benzocaine gel
Walmart

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.

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 methoglobinemia, 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 immeditate 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

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

Directions * cut open tip of tube on score mark * adults and children 2 years of age and older: apply a small amount 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 teh 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 untill 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

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

saccharin, sorbic acid

4x Medicated

Toothache & Gum

Relief Gel

*20'% Benzocaine to relieve oral pain

*Kills harmful bacteria

*Astringent to help prevent infection

*Cools gumm and relieves irritation

Fast Acting Gel

Compare to Orajel 4x Medicated for Toothache and Gum Gel Active Ingredients

4X MEDICATED TOOTHACHE AND GUM GEL

benzocaine gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49035-569
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
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.5 g in 100 g

Inactive Ingredients

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

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:49035-569-99	1 g in 1 TUBE; Type 0: Not a Combination Product	05/18/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	05/18/2020	

Labeler - Walmart (051957769)

Registrant - Lornamead (080046418)

Establishment

Name	Address	ID/FEI	Business Operations

Lornamead		080046418	manufacture(49035-569)