

4X MEDICATED SEVERE TOOTHACHE AND GUM GEL- benzocaine gel Rite Aid

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.

Active Ingredients Purpose

Benzalkonium Chloride 0.13% Oral Antiseptic

Benzocaine 20% Oral Pain Reliever

Menthol 0.5% Oral Pain Reliever

Zinc Chloride 0.15% Oral Astringent

Use

Use * 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 ay cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in teh 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 lightneadedness * 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

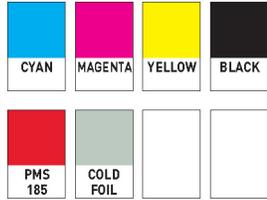
Do not use * more than directed * for more than 7 days unless told to do so by a dentist or doctor * for teething * in children under 2 years of age

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 to score mark * adults and children 2 years of age and older: apply a small amount of product to teh 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

LORNAMEAD, INC.		PROJECT INFO PRODUCTION NOTES			
DATE:	APRIL 27, 2020		APPROVALS CREATIVE _____ MARKETING _____ R&D _____ QUALITY _____ PURCHASING _____ CEO _____		
PROJECT:	RITE AID 4X MEDICATED TOOTHACHE GEL				
ITEM #:	2821615R1				
DIELINE #:	S170273				
SIZE:	1.031" X 1.031" X 3.500"				
FILE NAME:	RA_4XMEDICATED_TOOTHACHE_GEL_CTN_2821615R1-0L AI				
PRINTER:	MODPAC				
NOTE(S):					
<small>NEW YORK OFFICE 1359 BROADWAY 17TH FLOOR NEW YORK, NY 10018 TONAWANDA OFFICE 175 COOPER AVENUE TONAWANDA, NEW YORK 14150</small>					

Toothache & Gum Reliever

20% Benzocaine to relieve oral pain

Antiseptic to kill harmful bacteria

Astringent to help prevent infection

Menthol to soothe gums

4x medicated

Oral antiseptic/pain reliever/astringent

Net Wt 0.25 oz (7g)

4X MEDICATED SEVERE TOOTHACHE AND GUM GEL

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-0615
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
ZINC CHLORIDE (UNII: 86Q357L16B) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	0.15 g in 100 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.5 g in 100 g
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	20 g in 100 g

Inactive Ingredients

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

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:11822-0615-9	1 in 1 CARTON	05/06/2020	
1		7 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	05/06/2020	

Labeler - Rite Aid (014578892)

Registrant - Lornamead (080046418)

Establishment

Name	Address	ID/FEI	Business Operations
Lornamead		080046418	manufacture(11822-0615)