4X MEDICATED SEVERE TOOTHACHE AND GUM CREAM- benzocaine cream 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 Ingredient Purpose

Belkonium chloride 0.13% Oral antiseptic

Benzocaine 20% Oral pain reliever

Menthol 0.26% 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 may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces teh 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 * symtoms 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

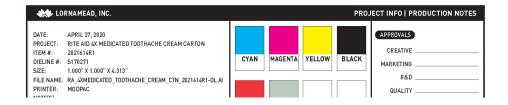
Directions * cut open tip of tube on score mark * dults and children 2 years of age and older; apply a small amount of product to the cavity and around teh gum surrounding the teeth. Use up to 4 times daily or as directed by a dentist or doctor * children under 12 years of age should be supervised in the use of this product * children under 2 years of age: do not use

Other information * do not use if the 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

Inactive ingredients ammonium glycyrrhizate, flavor, PEG-8, PEG-75, sodium saccharin, sorbic acid, titanium dioxide

4.313 0.875 NDC 11822-0614-9 Compare to the active ingredients in Orajel* 4X Medicated Cream CREAM 1.813 **TOOTHACHE & GUM RELIEVER** 20% BENZOCAINE TO RELIEVE ORAL PAIN ANTISEPTIC TO KILL HARMFUL BACTERIA ASTRINGENT TO HELP PREVENT INFECTION MENTHOL TO SOOTHE GUMS **TOOTHACHE & GUM RELIEVER** ORAL ANTISEPTIC/PAIN RELIEVER/ASTRINGENT 4X MEDICATED 7.594 NET WT 0.33 OZ (9.4 g) 2821614R1 5820614 2.781 .25 9 .187

LORNAMEAD 1.000 X 1.000 X 4.313 - PRINTSIDE SBS S170271 - 3/9/17



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 0.33 oz (9.4 g)

4X MEDICATED SEVERE TOOTHACHE AND GUM CREAM

benzocaine cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-0614
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BENZO CAINE (UNII: U3RS Y48 JW5) (BENZO CAINE - UNII: U3RS Y48 JW5)	BENZOCAINE	20 g in 100 g	
MENTHOL (UNII: L7T10 EIP3A) (MENTHOL - UNII:L7T10 EIP3A)	MENTHOL	0.26 g in 100 g	
ZINC CHLORIDE (UNII: 86Q357L16B) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	0.15 g in 100 g	
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKO NIUM - UNII:7N6 JUD5X6 Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g	

Inactive Ingredients		
Ingredient Name	Strength	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)		
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		
AMMO NIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)		
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)		
SORBIC ACID (UNII: X045WJ989B)		

Product Characteristics		
Color	white	Score
Shape		Size
Flavor	WINTERGREEN	Imprint Code

Contains

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:11822-0614-9	1 in 1 CARTON	05/06/2020	
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	05/06/2020	

Labeler - Rite Aid (014578892)

Establishment				
Name	Address	ID/FEI	Business Operations	
Lornamead		080046418	manufacture (118 22-0 6 14)	

Revised: 5/2020 Rite Aid