

3X MEDICATED 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

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 minor irritation or injury of the mouth and gums

Methemoglobinemia warning: use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen in the 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

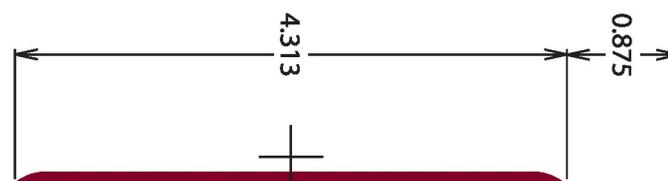
Keep out of reach of children In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

Directions * cut open tip of tube on score mark * do not use if tip is cut prior to opening * adults and children 2 years of age and older: apply to affected area 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 at least one hour after applying

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



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



		PROJECT INFO PRODUCTION NOTES																															
DATE: APRIL 27, 2020 PROJECT: RITE AID 3X MEDICATED TOOTHACHE GEL CARTON ITEM #: 2821613R1 DIELINE #: S170271 SIZE: 1.000" X 1.000" X 4.313" FILE NAME: RA_3XMEDICATED_TOOTHACHE_GEL_CTN_2821613R1-01.AI PRINTER: MODPAC NOTE(S):	<table border="1"> <tr> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>CYAN</td> <td>MAGENTA</td> <td>YELLOW</td> <td>BLACK</td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>PMS 202</td> <td>COLD FOIL</td> <td></td> <td></td> </tr> </table>					CYAN	MAGENTA	YELLOW	BLACK					PMS 202	COLD FOIL			<table border="1"> <tr> <th colspan="2">APPROVALS</th> </tr> <tr> <td>CREATIVE</td> <td>_____</td> </tr> <tr> <td>MARKETING</td> <td>_____</td> </tr> <tr> <td>R&D</td> <td>_____</td> </tr> <tr> <td>QUALITY</td> <td>_____</td> </tr> <tr> <td>PURCHASING</td> <td>_____</td> </tr> <tr> <td>CEO</td> <td>_____</td> </tr> </table>		APPROVALS		CREATIVE	_____	MARKETING	_____	R&D	_____	QUALITY	_____	PURCHASING	_____	CEO	_____
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NEW YORK OFFICE 1359 BROADWAY 17TH FLOOR NEW YORK, NY 10018 TONAWANDA OFFICE 175 COOPER AVENUE TONAWANDA, NEW YORK 14150																																	

Toothache and Gum Reliever

20% benzocaine to relieve oral pain

Astringent to help prevent infection

Menthol to soothe gums

3x medicated

oral pain reliever/astringent

Net Wt 0.42 oz (11.9 g)

3X MEDICATED TOOTHACHE AND GUM GEL

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-0613
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
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.26 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 3350 (UNII: G2M7P15E5P)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SORBIC ACID (UNII: X045WJ989B)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	

Product Characteristics

Color	white (Cloudy white to beige)	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-0613-9	1 in 1 CARTON	05/06/2020	
1		11.7 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)

Establishment

Name	Address	ID/FEI	Business Operations
Lornamead		080046418	manufacture(11822-0613)

Revised: 5/2020

Rite Aid