

NIGHTTIME 4X MEDICATED CREAM- benzocaine paste
Rite Aid

5820632 Rite Aid Nighttime Toothache & Gum (8015632)

Benzalkonium chloride 0.13%

Benzocaine 20%

Menthol 0.26%

Zinc chloride 0.15%

oral antiseptic

oral pain reliever

oral astringent

- for temporary relief of pain due to toothaches
- to help protect against infection of minor oral irritation

Methemoglobinemia warning: use of this product may cause methemoglobinemia, 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 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.

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

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

ammonium glycyrrhizate, chamomile, flavor, mineral oil, PEG-8, PEG-75, sodium saccharin, sorbic acid, titanium dioxide

cut open tip of tube on score mark

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 between 2 and 12 years of age: ask a doctor before use. Should be supervised in the use of this product.

children under 2 years of age: do not use

Do not use:

- more than directed
- for more than 7 days unless told do so by a dentist or doctor
- for teething
- in children under 2 years of age



NIGHTTIME 4X MEDICATED CREAM			
benzocaine paste			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-6300
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	
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	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.26 g in 100 g	

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
CHAMOMILE (UNII: FGL3685T2X)	
SORBIC ACID (UNII: X045WJ989B)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor	WINTERGREEN (Cloudy white to yellow)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-6300-1	1 in 1 CARTON	12/01/2024	
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 Drug	M017	12/01/2024	

Labeler - Rite Aid (014578892)

Registrant - Lornamead (080046418)

Establishment

Name	Address	ID/FEI	Business Operations
Lornamead		080046418	manufacture(11822-6300) , pack(11822-6300)