

RITE AID SEVERE TOOTHACHE AND GUM RELIEF TRIPLE MEDICATED- benzocaine, menthol, zinc chloride 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.

Rite Aid Triple Medicated Severe Toothache & Gum Relief Cream

Drug Facts

Active ingredient

Benzocaine 20%

Menthol 0.25%

Zinc Chloride 0.15%

Purpose

Oral pain reliever

Oral pain reliever

Astringent

Use

- for the temporary relief of oral pain due to minor irritation or injury of the mouth and gums

Warnings

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

Do not use

- more than directed
- for more than 7 days unless directed 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 on score mark
- **adults and children 2 years of age and older:** apply a small amount of the 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 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 cellulose gum, gelatin, methyl salicylate, mineral oil, pectin, petrolatum, polyethylene glycol, sodium saccharin

DISTRIBUTED BY:

RITE AID

30 HUNTER LANE

CAMP HILL, PA 17011

TAMPER EVIDENT: Carton is sealed for your protection.

RITE AID® PHARMACY

SEVERE **toothache & gum relief**

ORAL PAIN RELIEVER; ASTRINGENT

immediate relief of intense pain

Long lasting CREAM

triple medicated

- 20% Benzocaine for toothache pain relief
- Astringent to relieve gum irritation
- Menthol to soothe gums

NET WT 0.33 OZ (9.4g)

Compare to the active ingredients in Orajel® Severe Toothache Pain Relief

SEVERE
toothache & gum relief
immediate relief of intense pain

Long lasting **CREAM**
ORAL PAIN RELIEVER / ASTRINGENT

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TAMPER-EVIDENT:
Do not use if tip is cut prior to use.

**SATISFACTION
GUARANTEE**
If you're not satisfied,
we'll happily exchange
your money.

This product is not manufactured or distributed by
Church & Dwight Co., Inc, owner of the registered
trademark Orajel®.

0 11822 21439 1

Drug Facts

Active Ingredient Zinc Chloride 0.15%

Purpose Oral pain reliever

Warnings Use of this product may cause numbness/tingling, a numb condition that must be treated promptly because it reduces the amount of oxygen that is used for breathing. Stop use and seek immediate medical attention if you or child in your care develops: pale, gray, or blue colored skin (lips/mouth), a rigid or swollen neck, or a rigid neck. Stop use and seek immediate medical attention if you or child in your care develops: dizziness or lightheadedness, bluish or black stools, or numbness or tingling.

Use For the temporary relief of oral pain due to minor irritation or injury of the mouth and gums.

Directions Adults and children 2 years of age and older: Apply a small amount of product to the cavity and around the gum surrounding the tooth. Use up to 4 times daily or as directed by a dentist or doctor. Children under 2 years of age: Do not use.

Other Information Do not use if tip is cut prior to opening. This preparation is flammable 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 eating, drinking or chewing soft foods or hot liquids for at least one hour after applying.

Inactive Ingredients Colloidal cotton, gum, glycerin, methyl salicylate, menthyl oil, pectin, preservatives, polyethylene glycol, sodium ascorbate.

RITE AID SEVERE TOOTHACHE AND GUM RELIEF TRIPLE MEDICATED		
benzocaine, menthol, zinc chloride cream		
Product Information		
Product Type	HUMAN OTC DRUG	Item Code (Source)
Route of Administration	TOPICAL	NDC:11822-6037
Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength

ZINC CHLORIDE (UNII: 86Q357L16B) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	0.15 g in 100 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.25 g in 100 g
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	20 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
PETROLATUM (UNII: 4T6H12BN9U)	
MINERAL OIL (UNII: T5L8T28FGP)	
PECTIN (UNII: 89NA02M4RX)	
GELATIN (UNII: 2G86QN327L)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-6037-9	1 in 1 CARTON	03/04/2019	
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	03/04/2019	

Labeler - Rite Aid (014578892)

Registrant - Lornamead Inc. (080046418)

Establishment

Name	Address	ID/FEI	Business Operations
Lornamead Inc.		080046418	manufacture(11822-6037)

