

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

Rite Aid Severe Toothache & Gum Relief Gel Triple Med

Drug Facts

Active ingredients

Benzocaine 20%

Menthol 0.5%

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 between 2 and 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 blue 1, cellulose gum, gelatin, methyl salicylate, mineral oil, pectin, petrolatum, polyethylene glycol, sodium saccharin

DISTRIBUTED BY:

RITE AID

30 HUNTER LANE

CAMP HILL, PA 17011

RITE AID® PHARMACY

SEVERE

toothache & gum relief

immediate relief of intense pain

fast acting GEL

ORAL PAIN RELIEVER / ASTRINGENT

triple medicated

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

NET WT 0.25 OZ (7.0 g)



*Compare to Orajel™ Severe Toothache & Gum Relief Plus Triple Medicated Gel

SEVERE toothache & gum relief

immediate relief of intense pain

fast acting **GEL**
ORAL PAIN RELIEVER / ASTRINGENT

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30 HUNTER LANE
CAMP HILL, PA 17011



IF YOU'RE NOT SATISFIED,
WE'LL HAPPILY REFUND
YOUR MONEY.



0 11822 59363 2

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

This product is not manufactured or distributed by Church & Dwight Co., Inc., makers of Orajel™.

Inactive ingredients Blue 1, cellulose gum, glycerin, methyl salicylate, mineral oil, pectin, polybutene, polyethylene glycol, sodium saccharin.

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

Directions • cut open tip of tube on score mark • 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 between 2 and 12 years of age should be supervised in the use of this product • children under 2 years of age: do not use

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. Stop use and ask a doctor if 7 days • swelling, rash or fever develops • irritation, pain or redness persists or worsens • symptoms do not improve in 7 days • allergic reaction occurs

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

Warnings • 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 the product before. Stop use and seek immediate medical attention if you or a child in your care develops:

• pale, gray, or blue colored skin (pallor) • headache • rapid heart rate • shortness of breath • dizziness or lightheadedness • fatigue or lack of energy

Adverse effects do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics.

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

Zinc Oxide 0.15%
Menthol 0.5%
Benzocaine 20%
Oral pain reliever
Oral pain reliever
Menthol

Drug Facts
Active ingredients
Purpose

RITE AID SEVERE TOOTHACHE AND GUM RELIEF TRIPLE MEDICATED

benzocaine, menthol, zinc chloride gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-6038
Route of Administration	TOPICAL		

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	0.5 g in 100 g
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	20 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
PETROLATUM (UNII: 4T6H12BN9U)	
MINERAL OIL (UNII: T5L8T28FGP)	
PECTIN (UNII: 89NA02M4RX)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
GELATIN (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

Product Characteristics

Color	blue	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-6038-9	1 in 1 CARTON	03/04/2019	
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	03/04/2019	

Labeler - Rite Aid (014578892)

Registrant - Lornamead Inc. (080046418)

Establishment

Name	Address	ID/FEI	Business Operations
Lornamead Inc.		080046418	manufacture(11822-6038)

Revised: 1/2023

Rite Aid