

RITE AID MAXIMUM TOOTHACHE RELIEVER- benzocaine, menthol 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 Maximum Toothache Relief Double Med Gel

Drug Facts

Active ingredient

Benzocaine 20%

Menthol 0.26%

Purpose

Oral Pain Reliever

Oral Pain Reliever

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 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 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

- 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, Polyethylene Glycol, Sodium Saccharin, Sorbic Acid

DISTRIBUTED BY:

RITE AID

30 HUNTER LANE

CAMP HILL, PA 17011

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

RITE AID® PHARMACY

MAXIMUM toothache reliever

immediate relief of toothache pain

Fast acting GEL

ORAL PAIN RELIEVER

Double Medicated

- 20% Benzocaine for toothache pain relief
- Menthol to sooth gums

NET WT 0.42 OZ (12 g)





Compare to the active ingredients in
OrajelTM Maximum Toothache Pain Relief
Double Medicated Gel*

MAXIMUM toothache reliever

immediate relief of toothache pain

Fastacting GEL

ORAL PAIN RELIEVER

double medicated

- 20% Benzocaine for toothache pain relief
- Menthol to soothe gums

double medicated

- 20% Benzocaine for toothache pain relief
- Menthol to soothe gums

DISTRIBUTED BY:
RITE AID
30 HUNTER LANE
CAMP HILL, PA 17011

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



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

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



0 11822 68027 1

Drug Facts

Active Ingredient
Benzocaine 20%
Menthol 0.26%
Oral Pain Reliever

Purpose
Oral Pain Reliever

Warnings
The benzocaine warning: use of this product may cause methemoglobinemia, a serious condition that may be fatal if not promptly treated. 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.

Always alert do not use this product if you have a history of allergy to local anesthetics such as procaine, tetracaine, butabaine, benzocaine or other "saine" anesthetics.

Do not use • more than directed • for more than 7 days unless told to do so by a dentist or doctor • for numbing 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 top of tube on score mark • do not use if top 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 top 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 • the 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 Glycyrrhate, Flavor, Polyethylene Glycol, Sodium Starch Glycolate, Sorbic Acid

RITE AID MAXIMUM TOOTHACHE RELIEVER			
benzocaine, menthol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-6036
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.26 g in 100 g	

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

Inactive Ingredients

Ingredient Name	Strength
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBIC ACID (UNII: X045WJ989B)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ05DW1A)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-6036-9	1 in 1 CARTON	03/04/2019	
1		12 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(11822-6036)

Revised: 1/2023

Rite Aid