

**4X MEDICATED TOOTHACHE AND GUM GEL- benzocaine gel, dentifrice
Publix Super Markets INC**

5820631 Publix 4x Medicated Toothache & Gum Gel (8015602)

Drug Facts

Benzalkonium chloride 0.13%

Benzocaine 20%

Menthol 0.5%

Zinc Chloride 0.15%

Oral antiseptic

Oral pain reliever

Oral astringent

temporary relief of pain due to toothache * 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 lightheadness

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 or allergic reaction, 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 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: 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 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

ammonium glycyrrhizate, blue 1, flavor, PEG-8, PEG-75, sodium saccharin, sorbic acid

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PUBLIX SUPER MARKETS, 3300 PUBLIX CORPORATE PARKWAY

LAKELAND, FL 33811

PUBLIX SUPER MARKETS, INC

4X MEDICATED GEL

TOOTHACHE & GUM PAIN RELIEF

- 20% Benzocaine to relieve oral pain
- Kills harmful bacteria
- Astringent to help prevent infection
- Cools gum & relieves irritation

Compare to the active ingredients in Orajel

4X medicated for toothache & Gum gel*

NET WT 0.25OZ (7 g)



- Kills harmful bacteria
- Astringent to help prevent infection
- Cools gum & relieves irritation

Compare to the active ingredients in Orajel™
4X medicated for toothache & gum gel*

NET WT 0.25 OZ (7 g)

- Immediate relief of severe pain
- Fast-acting

ORAL ANTISEPTIC / PAIN RELIEVER /
ASTRINGENT

NET WT 0.25 OZ (7 g)

4X Medicated Gel Toothache & Gum Pain Relief

ORAL ANTISEPTIC / PAIN RELIEVER /
ASTRINGENT

NET WT 0.25 OZ (7 g)

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5820431

*This product is not manufactured or distributed by Church & Dwight Co., Inc., makers of Orajel™.
TAMPER-EVIDENT: Do not use if tube tip is cut prior to use.
Retain carton for complete product information.

Drug Facts
<p>Active ingredients</p> <ul style="list-style-type: none"> Benzocaine 20% Oral pain reliever Menthol 0.5% Oral pain reliever Zinc chloride 0.15% Oral astringent
<p>Use • for the temporary relief of pain due to toothaches • to help protect against infection of minor oral irritation</p>
<p>Warnings</p> <p>Metforman warning: use of this product may cause metforman-related, 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 (cyanosis) • headache • rapid heart rate • shortness of breath • dizziness or lightheadedness • fatigue or lack of energy</p> <p>Warnings: do not use this product if you have a history of allergy to local anesthetics such as procaine, tetracaine, butacaine or other "caine" anesthetics</p> <p>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</p> <p>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</p> <p>Keep out of reach of children. In case of overdose or allergic reaction, get medical help or contact a Poison Control Center right away.</p>
<p>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: use a doctor before use. Should be supervised in the use of this product • children under 2 years of age: do not use</p> <p>Other information • do not use if tip is cut prior to opening • this preparation is intended for use in cases of toothaches, 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</p> <p>Inactive ingredients ammonium glycyrrhizate, zinc 1, thioctic acid, PEG-8, PEG-15, sodium saccharin, saccharic acid</p>
<p>Purpose</p> <ul style="list-style-type: none"> Oral analgesic Oral pain reliever Oral astringent

4X MEDICATED TOOTHACHE AND GUM GEL

benzocaine gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56062-312
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
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 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	0.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
SORBIC ACID (UNII: X045WJ989B)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	

Product Characteristics

Color	blue (blue to Blue Green)	Score	
Shape		Size	
Flavor	WINTERGREEN	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56062-312-22	1 in 1 CARTON	09/01/2024	
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	M022	09/01/2024	

Labeler - Publix Super Markets INC (006922009)

Registrant - Lornamead Inc (080046418)

Establishment

Name	Address	ID/FEI	Business Operations
Lornamead		080046418	pack(56062-312) , manufacture(56062-312)

Revised: 10/2024

Publix Super Markets INC