

PM TOOTHACHE RELIEF- benzocaine cream CVS

5820625 CVS Health 4x Medicated Cream PM

For the temporary relief of pain due to toothaches. To help protect against infection of minor oral irritation.

ammonium glycyrrhizate, chamomile, flavor, mineral oil, PEG-8, PEG-77, 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 under 12 years of age should be supervised in the use of this product. Children under 2 years of age: do not use.

Belzalkonium Chloride 0.13% Oral antiseptic

Benzocaine 20% Oral pain reliever

Methol 0.26% Oral pain reliever

Zinc chloride 0.15% Oral astringent

Keep out of reach of children. In case of overdose, get medical help or contact a POison Control Center right away.

Do not use if tube 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.

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.

Principal Display Panel

20% benzocaine to relieve oral pain

Kills harmful bacteria

Astringent to help prevent infection

Cools gums and relieves irritation

Net Wt 0.25 oz (7g)



Compare to the active ingredients
in Orajel™ 4X Medicated For
Toothache & Gum Cream Nighttime*

PM Toothache & Gum Pain Relief Cream

4X MEDICATED

Nighttime formula with chamomile

- 20% BENZOCAINE to relieve oral pain
- ANTISEPTIC to kill harmful bacteria
- ASTRINGENT to help prevent infection
- MENTHOL to soothe the gums



- Immediate relief of severe toothache & gum pain
- Long-lasting cream

NIGHTTIME FORMULA with chamomile

PM Toothache & Gum Pain Relief Cream



Cream

Oral Antiseptic; Pain Reliever; Astringent

NET WT 0.25 OZ (7 g)

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Retain carton for complete product information.
TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGING IS MISSING OR BROKEN.
*This product is not manufactured or distributed by Church & Dwight Co., Inc., makers of Orajel™.

menemogioinemia warning: use of this product may cause menemogioinemia, 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

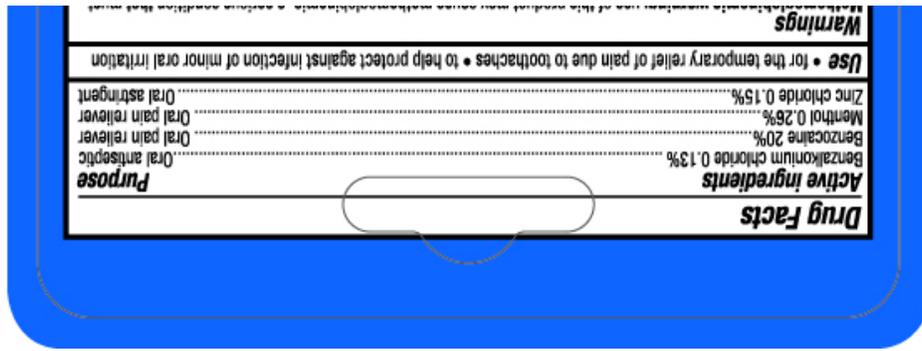
Stop use and ask a doctor if • swelling, rash or fever develops • irritation, pain or redness persists or worsens • symptoms do not improve in 7 days • allergic reaction occurs

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



PM TOOTHACHE RELIEF

benzocaine cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-623
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	20 g in 100 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.26 g in 100 g
ZINC CHLORIDE (UNII: 86Q357L16B) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	0.15 g in 100 g
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g

Inactive Ingredients

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

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-623-09	1 in 1 BOX	11/17/2023	
1		7.1 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	11/17/2023	

Labeler - CVS (062312574)

Registrant - Lornamead (080046418)

Establishment

Name	Address	ID/FEI	Business Operations
Lornamead		080046418	manufacture(69842-623) , pack(69842-623)

Revised: 11/2023

CVS