4X MEDICATED SEVERE TOOTHACHE AND GUM GEL- benzalkonium chloride gel
Meijer

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.

5820610 Meijer 4X Medicated Toothache & Gum Gel

Benzalkonium chloride 0.13% .....Oral antiseptic

Benzocaine 20% .....Oral pain reliever

Menthol 0.5% .....Oral pain reliever

Zinc chloride 0.15% .....Oral astringent

Use

for the temporary relief of pain due to toothaches

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 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

• 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

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 children under 12 years of age should be supervised in the use of this product • children under a dentist or doctor • 2

years of age: do not use

Other Information

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

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

NDC 41250- 061-19

*Compare to the active ingredient in Orajel™ 4X Medicated For Toothache & Gum Gel

4X MEDICATED

toothache & gum

pain relief gel

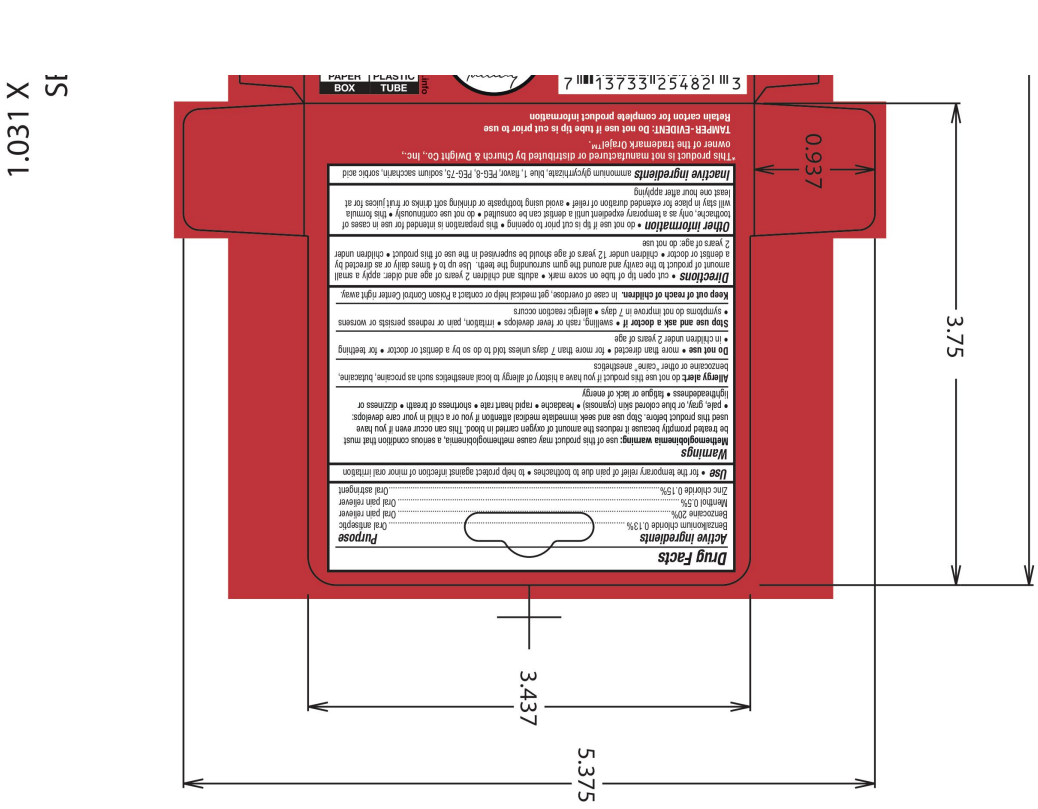
Immediate Pain Relief

20% Benzocaine to Relieve Oral Pain

Antiseptic to Kill Harmful Batceria

Astringent to Help Prevent Infection

Menthol to cool Gum & Relieves Irritation



4X MEDICATED SEVERE TOOTHACHE AND GUM GEL

benzalkonium chloride gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:79481-0610
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	20 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)	
SORBIC ACID (UNII: X045WJ989B)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	

Product Characteristics

Color	blue	**Score**	
Shape		**Size**	
Flavor	WINTERGREEN	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79481-0610-9	1 in 1 CARTON	11/20/2019	
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	11/20/2019	

Labeler - Meijer (006959555)

Establishment

Name	Address	ID/FEI	Business Operations
Lornamead		080046418	manufacture(79481-0610) , pack(79481-0610)

Revised: 8/2023 Meijer