

ORAL PAIN RELIEF- benzocaine gel
Nantong Health & Beyond Hygienic Products Inc.

43473-100-01, Fast-Acting ORAL PAIN RELIEF GEL

Drug facts

Active ingredients

Benzocaine 20%

Purposes

Oral pain reliever

Uses

• for the temporary relief of pain due to toothaches • to help protect against infection in 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

Do not use • more than directed • for more than 7 days unless directed by a physician or healthcare provider

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

Keep out of reach of children. in case of overdose or allergic reaction, get medical help

Directions

• Adults and children 2 years of age and over: Apply a small amount of product to the cavity and around gum surrounding the teeth. Use up to 4 times daily or as directed by a physician or healthcare provider • 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

- this preparation is intended for use in cases of toothache, only as a temporary expedient until a physician can be consulted
- do not use continuously
- avoid using toothpaste or drinking soft drinks or fruit juices for at least one hour after applying
- do not use if tube seal under cap is broken, missing or if the tube tip is cut prior to opening

Inactive ingredients

Ammonium Glycyrrhizate, Fragrance, Polyethylene Glycol 400, Polyethylene Glycol 4000, Saccharin Sodium, Sorbic Acid, Water

COOLING COMFORT FORMULA

- **FAST COOLING**
- **TOOTH & GUM COMFORT**

For Pain Relief & Toothaches

Mfd for and Distributed by:

Universal Distribution Center LLC
330 Applegarth Road,
Monroe Township, NJ 08831

www.universaldc.com

MADE IN CHINA

Packaging

Outer Package Label





Inner Package Label



<p>ORAL PAIN RELIEF benzocaine gel</p>	
<p>Product Information</p>	

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43473-100	
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	
Inactive Ingredients				
Ingredient Name			Strength	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)				
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)				
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HFI6D95)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
SORBIC ACID (UNII: X045VJ989B)				
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43473-100-04	1 in 1 BOX	03/11/2026	
1		11.9 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	01/20/2026		

Labeler - Nantong Health & Beyond Hygienic Products Inc. (421280161)

Establishment

Name	Address	ID/FEI	Business Operations
Nantong Health & Beyond Hygienic Products Inc.		421280161	manufacture(43473-100)

Revised: 3/2026

Nantong Health & Beyond Hygienic Products Inc.