

ORAL GEL ORAL PAIN RELIEF- benzocaine benzalkonium chloride gel

Savvy Care and Cosmetics

Oral gel

Active Ingredient

Benzocaine 20%

Benzalkonium Chloride 0.1%

Purpose

Oral pain reliever

Antiseptic

Use

■ for the temporary relief of pain due to toothaches ■ to help protect against infection in minor oral irritation

Warnings

■ **Allergy alert:** do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine or other "caine" anesthetics

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 or contact a Poison Control Center right away

Directions

■ adults and children 2 years of age and over: apply a small amount of the product to the cavity and around the gum surrounding the teeth Use up to 4 times daily or as

directed by a physician or healthcare provider ■ children under 12 years: should be supervised in the use of this product ■ children under 2 years of age: ask a physician or health care provider

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, flavor, polyethylene glycol, sodium saccharin, sorbic acid

Package Label



Drug Facts

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Benzocaine 20% Oral pain reliever
Benzalkonium Chloride 0.1% Antiseptic

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Drug Facts (continued)

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

Specially Manufactured for DELTA BRANDS INC., Larchmont, NY 10538 www.deltabrands.com ITEM NO: 10373 / MADE IN INDIA 10373/01(007)

ORAL GEL ORAL PAIN RELIEF

benzocaine benzalkonium chloride gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:83650-101

Route of Administration		TOPICAL		
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	0.1 g in 100 g	
Inactive Ingredients				
Ingredient Name			Strength	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
SORBIC ACID (UNII: X045WJ989B)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83650-101-01	42.5 g in 1 TUBE; Type 0: Not a Combination Product	09/22/2023	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug		M022	09/22/2023	

Labeler - Savvy Care and Cosmetics (915039748)

Establishment			
Name	Address	ID/FEI	Business Operations
Savvy Care and Cosmetics		915039748	manufacture(83650-101)