# HEALTH-TEC TOPICAL ANESTHETIC- benzocaine gel Dental Health Products, Inc.

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.

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# **Active Ingredients**

Benzocaine 200mg (in each g)

## Purpose

Oral Anesthetic

#### Use

For oral mucosal use only, as directed by dentist. For the temporary relief of pain due to minor dental procedures.

# 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 the 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 on patients with a history of allergies to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics.

## Do not use

- for more than 7 days unless directed by a physician. If sore mouth symptoms do not improve in 7 days; irritation, pain, or redness persists or worsens; or if swelling, rash or fever develops, see your physician promptly.
- for teething
- in children under 2 years of age

When using this product Avoid contact with eyes. If contact occurs, flush with water.

**Do not exceed recommended dosage.** If more than used for pain is accidentally swallowed, get medical help or contact a Poison Control Center right away.

If pregnant or breast feeding, ask a physician before use.

#### Directions

- Apply only amount needed to the oral mucosa to prevent or relieve pain.
- children under 2 years of age: do not use

### Keep out of reach of children.

#### Other Information

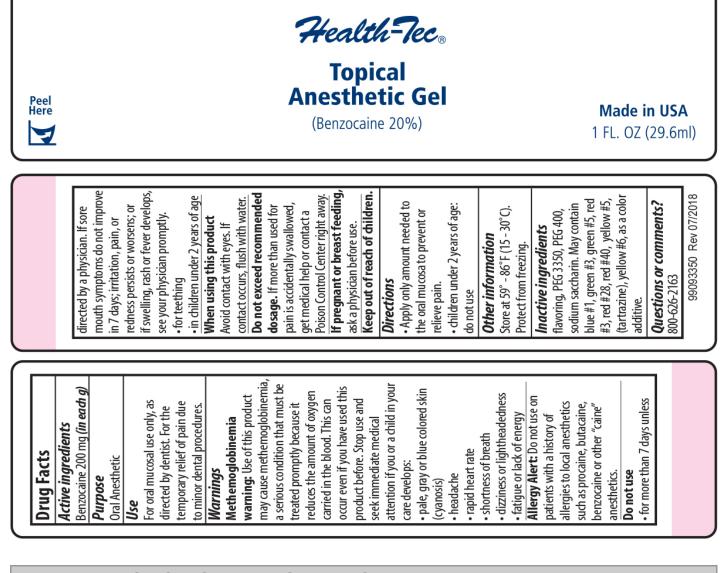
Store at 59°-86°F (15°-30°C). Protect from freezing.

#### **Inactive Ingredients**

flavoring, PEG 3350, PEG 400, sodium saccharin. May contain blue #1, green #3, green #5, red #3, red #28, red #40, yellow #5, (tartrazine), yellow #6, as a color additive.

#### **Questions of comments?**

800-626-2163



HEALTH-TEC TOPICA benzocaine gel	L ANESTHETIC				
Product Information					
Product Type	HUMAN OTC DRUG	Item Code	(Source)	NDC	:69634-025
Route of Administration	DENTAL				
Active Ingredient/Active	Moiety				
Ingredient Name			<b>Basis of Strength</b>		Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)			BENZOCAINE		200 mg in 1 g
Inactive Ingredients					
	Ingredient Name				Strength
POLYETHYLENE GLYCOL 3350 (	UNII: G2M7P15E5P)				
POLYETHYLENE GLYCOL 400 (U	NII: B697894SGQ)				

SACCHARIN SODIUM (UNII: SB8ZUX40TY)

	5 (UNII) 1753M	/B2F1M)							
	FD&C YELLOW NO. 5 (UNII: 1753WB2F1M) FD&C YELLOW NO. 6 (UNII: H77VEI93A8)								
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)									
FD&C RED NO. 40 (UNII: WZB9127XOA)									
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)									
FD&C GREEN NO. 3 (UNII: 3P3ONR601S)									
D&C RED NO. 28 (UNII: 767IP0Y5NH)									
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)									
Product Charac	teristics								
Color		purple Score							
			Size						
· · ·		GRAPE	Imprint Code						
Contains			-						
Packaging									
# Item Code	Pac	Package Description		Ν	larketing Start Date	Marketing End Date			
NDC:69634-025- 30 30 g in 1 JAR; Type 0: Not a Combination Product 07/01/2018									
Marketing Information									
Marketing Category	Applicat	ion Number or Mo Citation	nograph	ı	Marketing Start Date	Marketing End Date			
OTC monograph not final	part356				04/01/2015				

Labeler - Dental Health Products, Inc. (623191194)

Revised: 1/2022

Dental Health Products, Inc.