# **DENTEK INSTANT PAIN RELIEF MAXIMUM STRENGTH-** benzocaine liquid DenTek Oral Care, Inc.

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DenTek Instant Pain Relief 60630-078-01

# **Drug Facts**

# Active ingredient

Benzocaine 20%

# **Purpose**

Oral pain reliever

#### Use

for the temporary relief of pain due to:

- toothaches
- canker sores
- cold sores
- sore gums

# 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

**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. If a skin reaction occurs, stop use and seek medical help right away.

#### Do not use

- for teething
- in children under 2 years of age

# When using this product

- avoid contact with the eyes
- do not exceed recommended dosage
- do not use for more than 7 days unless directed by a doctor/dentist

# Stop use and ask a dentist or doctor 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, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

#### **Directions**

dip applicator into liquid

Adults and children 2 years and older	Apply a small amount of product to the affected area. Use up to 4 times daily or as directed by a dentist or doctor.
Children between 2 and 12 years	Should be supervised in the use of this product.
Children under 2 years	Do not use.

#### Other information

- for toothaches, use only as a temporary remedy until a dentist can be seen
- store at 20-25°C (68-77°F).

# Inactive ingredients

Peppermint Oil, Polyethylene Glycol 400, Spearmint Oil, Sucralose

## PRINCIPAL DISPLAY PANEL

DenTek™

#### **INSTANT PAIN RELIEF**

Benzocaine 20% / ORAL ANESTHETIC

1 BOTTLE OF BENZOCAINE 0.118 fl oz (3.5 mL), 1 CASE, 50 APPLICATORS, 1 HANDLE



### **DENTEK INSTANT PAIN RELIEF MAXIMUM STRENGTH**

benzocaine liquid

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:60630-078

**Route of Administration** DENTAL, TOPICAL

# **Active Ingredient/Active Moiety**

Ingredient Name

BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)

BENZOCAINE

BENZOCAINE

BENZOCAINE

200 mg in 1 mL

# Inactive Ingredients Ingredient Name Strength PEPPERMINT OIL (UNII: AV092KU4JH) POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) SPEARMINT OIL (UNII: C3M81465G5) SUCRALOSE (UNII: 96K6UQ3Z D4)

Product Characteristics					
Color	yellow (colorless to light yellow liquid)	Score			
Shape		Size			
Flavor	MINT (Fresh Mint)	Imprint Code			
Contains					

Packaging					
4	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:60630- 078-01	1 in 1 CARTON	07/31/2015		
1	L	3.5 mL in 1 VIAL, GLASS; 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	07/31/2015			

# Labeler - DenTek Oral Care, Inc. (153818646)

Revised: 6/2025 DenTek Oral Care, Inc.