

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

DENTEK INSTANT PAIN RELIEF

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.

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

**MAXIMUM
STRENGTH**

DentekTM

DKUS1063101

disposable
applicators



INSTANT PAIN RELIEF

BENZOCAINE 20% / ORAL ANESTHETIC

RELIEVES ORAL PAIN & TOOTHACHES

NO FINGERS NO MESS



SANITARY



DISPOSABLE



PRECISE

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

WARNING: Choking Hazard– Small parts. Keep Applicators out of reach of children under 3.



800-4DENTEK(433-6835)
DenTek.com

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



INCLUDES:



50
SINGLE USE
DISPOSABLE
APPLICATORS



1
HANDLE



1
BOTTLE
OF LIQUID
BENZOCAINE

+ 1 CARRYING CASE

Dist. by: DenTek Oral Care, Inc.
Tarrytown, NY 10591
A Prestige Brands Company
Made in USA. DKUS106T01
Patent Pending
©2018 Trade dress is owned
by DenTek Oral Care, Inc.
All rights reserved.

DENTEK INSTANT PAIN RELIEF MAXIMUM STRENGTH

benzocaine liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60630-077
Route of Administration	DENTAL, TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	200 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
-----------------	----------

PEPPERMINT OIL (UNII: AV092KU4JH)	2.2 mg in 1 mL
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	784.5 mg in 1 mL
SPEARMINT OIL (UNII: C3M81465G5)	3.3 mg in 1 mL
SUCRALOSE (UNII: 96K6UQ3ZD4)	10 mg in 1 mL

Product Characteristics

Color	yellow (colorless to light yellow liquid)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60630-077-04	1 in 1 CARTON	07/31/2015	
1	NDC:60630-077-03	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 not final	part356	07/31/2015	

Labeler - DenTek Oral Care, Inc. (153818646)

Registrant - DenTek Oral Care, Inc. (153818646)

Revised: 10/2021

DenTek Oral Care, Inc.