

DENTARIN- benzocaine 20% solution
Vitamex USA, Corp.

Active Ingredients:

Active Ingredients: Purpose

Benzocaine 20%..... Oral Pain Reliever

Uses:

Uses: Temporarily relieves pain caused by toothache, canker, sores, cold sores, fever blisters, minor irritation or injury of the mouth and gums.

Warnings: Methemoglobinemia warning:

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 heartbeat, shortness of breath, dizziness or lightheadedness, fatigue or lack of energy. **Keep away from eyes.**

Allergy alert

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 attention right away.

Flammability warning

Flammability warning: keep away from fire or flame

Do not use

Do not use: more than directed, for more than 7 days unless told to do so by a dentist or doctor, for teething, in children under 2 years of age.

Stop use and ask a doctor if

Stop use and ask a doctor if: sore mouth symptoms do not improve in 7 days, swelling, rash or fever develops, pain or redness persists or worsens.

If pregnant or breastfeeding

If pregnant or breastfeeding, ask a health professional before use

Keep out of reach of children

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions:

Adults and children 2 years of age older | Apply to affected area up to 4 times daily or as directed by dentist or doctor

Children under 12 years of age | Should be supervised in the use of this product

Children under 2 years of age | Do not use

Directions: Spray a small amount of product around the affected area up to 4 times daily.

Other information

Other information: Store at controlled room temperature: 15-30°C (59-86°F). Tamper Evident Feature: Do not use if cello-band over cap is torn, broken or missing.

Inactive ingredients

Inactive ingredients: alcohol, clove oil, glycerin, polyethylene glycol, propylene glycol, sodium methylparaben, sodium saccharin

Doseage and administration

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Dentarin

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Balsamo Dental En Spray

Helps relieve Toothache and Mouth Sores

Net Contents: 1 Fl. Oz (30mL)



DENTARIN

benzocaine 20% solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69469-200
Route of Administration	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
CLOVE OIL (UNII: 578389D6D0)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
METHYLPARABEN SODIUM (UNII: CR6K9C2NHK)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALCOHOL (UNII: 3K9958V90M)	

Product Characteristics

Color	yellow	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69469-200-30	30 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	08/01/2024	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC Monograph Drug	M022	08/01/2024	

Labeler - Vitamex USA, Corp. (054256676)

Revised: 8/2024

Vitamex USA, Corp.