ORABASE BENZOCAINE PURPLE ICE- benzocaine paste, dentifrice
Colgate Oral Pharmaceuticals, Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Orabase® 20% Benzocaine - Purple Ice

Drug Facts

Active ingredient

Benzocaine 20%

Purpose

Oral Pain Reliever

Use

for temporary relief of pain associated with canker sores, due to minor irritation or injury of the mouth and gums, or due to minor irritation of the mouth and gums caused by dentures or orthodontic appliances

Warnings

Do not use

- for more than 7 days unless directed by a dentist or physician
- if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine, or other "caine" anesthetics

When using this product

- do not exceed recommended dosage
- avoid contact with eyes
- localized allergic reactions may occur after prolonged or repeated use

Stop use and ask a doctor if

- sore mouth symptoms do not improve in 7 days
- swelling, rash or fever develops
- irritation, pain or redness persists or worsens

Keep out of reach of children. If more than used for pain relief is accidentally swallowed, get medical help or contact a Poison Control Center immediately.

Directions

- adults and children 2 years and older: gently dab paste on the site of irritation with a cotton swab or fingertip
- allow to remain in place at least 1 minute and then spit out
- use up to 4 times daily or as directed by a dentist or physician
- children under 12 years of age should be supervised in the use of the product
- children under 2 years of age: consult a dentist or physician

Other information

store at controlled room temperature, 68-77°F (20-25°C)

Inactive ingredients

mineral oil, cellulose gum, pectin, xanthan gum, polyethylene, flavor

Questions or comments?

call toll-free **1-800-962-2345**

PRINCIPAL DISPLAY PANEL - 11.9 g Tube Carton

Colgate®

Orabase®
20% Benzocaine

ALCOHOL FREE

Maximum Strength
Oral Pain Reliever

NET WT 0.42 OZ (11.9 g)

This Formula does not contain ethanol

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Drug Facts (continued)

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Rev. 04/12
038341106778

LOT:
EXP:

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Orabase®
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Maximum Strength
Oral Pain Reliever
ALCOHOL FREE
NET WT 0.42 OZ (11.9 g)

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20% Benzocaine
Maximum Strength
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ALCOHOL FREE

FAST RELIEF for CANKER & MOUTH SORES
PASTE
#1 Recommended by Pharmacists
Maximum strength relief for:
• Canker sores • Cheek bites • Toothbrush irritations
• Denture irritations • Orthodontic irritations
NEW Soothing Mint
ALCOHOL FREE

ORABASE BENZOCAINE PURPLE ICE

benzocaine paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0126-0082
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Benzocaine (UNII: U3RSY48JW5) (Benzocaine - UNII:U3RSY48JW5)	Benzocaine	19.8 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
Mineral Oil (UNII: T5L8T28FGP)	
Xanthan Gum (UNII: TTV12P4NEE)	
Carboxymethylcellulose Sodium (UNII: K679OBS311)	
Pectin (UNII: 89NA02M4RX)	
High Density Polyethylene (UNII: UG00KM4WR7)	
Isoxaflutole (UNII: 0T9R0O0EYT)	

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor	GRAPE, MINT	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0126-0082-04	12 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		08/01/2012	

Labeler - Colgate Oral Pharmaceuticals, Inc. (055002195)

Revised: 2/2013 Colgate Oral Pharmaceuticals, Inc.