

COMFORTCAINE TOPICAL ANESTHETIC- benzocaine gel
Mycone Dental Supply Co., Inc DBA Keystone Industries and Deepak 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.

Comfortcaine Mint

Active Ingredients (in each gram)

Benzocaine 200 mg

Purpose

Oral Anesthetic

Uses

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

Warnings

Allergy Alert: Do not use on patients with a history of allergies to local anesthetics such as benzocaine or other "caine" anesthetics.

Do not use

- for more than 7 days unless directed by a dentist or doctor.
- If sore mouth symptoms do not improve in 7 days
- irritation, pain, or redness persists or worsens
- if swelling, rash or fever develops, see your dentist or doctor promptly.

When using this product

Avoid contact with eyes. If contact occurs, flush with water.

Stop use and consult a health care practitioner

If the following symptoms appear: weakness, confusion, headache, difficulty breathing and/or pale, gray, or blue coloured skin, as these may be signs of methemoglobinemia, a rare disorder, which may appear up to 2 hours after use.

Do not exceed recommended dosage.

- If more than used for pain is accidentally swallowed, get medical help or contact a Poison Control Center immediately.

If pregnant or breast feeding,

ask a health professional before use.

Keep out of reach of children.

Directions

Apply only amount needed to the oral mucosa to prevent or relieve pain.

Other information

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

Inactive ingredients

Flavoring, polyethylene glycol base, sodium saccharin. May contain blue #1, red #3, red #33, red #40, yellow #6, yellow #10.

Questions or Comments?

1-800-333-3131 or 856-663-4700

www.keystoneind.com

Principle Display Panel

Bosworth ® ComfortCaine™

Topical Anesthetic

1 oz. (30g.)

BOSLAB-176 0516PR930

Bosworth ® Company

Manufactured for:

Harry J. Bosworth Company

A division of Keystone Industries

480 South Democrat Road

Gibbstown, NJ 08027

800.333.3131

www.keystoneindustries.com

Made in USA

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Manufactured for:
 The Henry J. Bosworth Company
 A division of Keystone Industries
 480 S. Democrat Road
 Gibbstown, NJ 08027

Drug Facts

Active ingredients (in each gram)
 Benzocaine 20mg

Purpose
 Topical Anesthetic

Use
 For oral use only, as directed. For temporary relief of pain due to minor dental procedures.

Warnings
Allergy Alert: Do not use on patients with a history of allergies to local anesthetics such as benzocaine or other "caine" anesthetics.

- Do not use: for more than 7 days or if symptoms do not improve in 7 days; - irritation, pain, or redness persists; or worsens

- If swelling, rash or fever develops, see your dentist or doctor promptly.

- When using this product: avoid contact with contact lenses. Flush with water.

- Stop use and consult a health care practitioner if the following symptoms appear: - weakness - confusion - pale, gray or blue colored skin, as these may be signs of

COMFORTCAINE TOPICAL ANESTHETIC

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68400-998
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RS Y48JW5) (BENZOCAINE - UNII:U3RS Y48JW5)	BENZOCAINE	200 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
MINT (UNII: FV98 Z8 G1TP)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
SACCHARIN SODIUM (UNII: SB8ZUX40 TY)	

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			
Product Characteristics			
Color		Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			
Packaging			
#	Item Code	Package Description	Marketing Start Date Marketing End Date
1	NDC:68400-998-01	30 g in 1 JAR; Type 0: Not a Combination Product	01/01/1997 08/31/2020
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	01/01/1997	08/31/2020

Labeler - Mycone Dental Supply Co., Inc DBA Keystone Industries and Deepak Products Inc (014769301)

Revised: 5/2018

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