VISTACAINE TOPICAL ANESTHETIC- benzocaine gel Inter-Med, 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.

Active Ingredients (in each gram)

Benzocaine 200 mg

Purpose

Oral Anesthetic

Use

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; or 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, grey or blue colored 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.

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Directions

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

Other Information

Store at 59º -86°F (15 - 30°C).

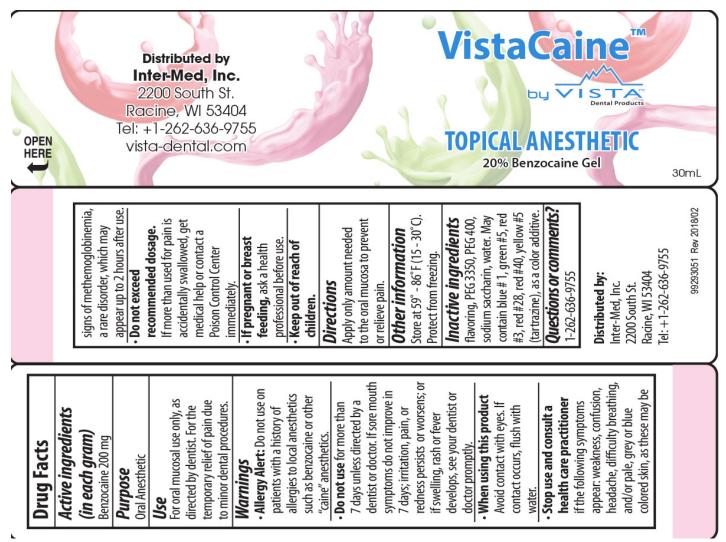
Protect from freezing.

Inactive ingredients

flavoring, PEG 3350, PEG 400, sodium saccharin, water. May contain blue #1, green #5, red #3, red #28, red #40, yellow #5 (tartrazine), as a color additive.

Questions or comments?

1-262-636-9755



VISTACAINE TOPICAL ANESTHETIC

benzocaine gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:64522-003

Route of Administration DENTAL

Active Ingredie	nt/Active Moiety		
Ingredient Name		Basis of Stre	ngth Strength
BENZOCAINE (UNII: U	J3RSY48JW5) (BENZOCAINE - UNII:U	3RSY48JW5) BENZ OCAINE	200 mg in 1
Inactive Ingred			a
Ingredient Name POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)			Strength
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) SACCHARIN SODIUM (UNII: SB8ZUX40TY)			
WATER (UNII: 059QFC			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)			
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)			
D&C RED NO. 28 (UNII: 767IP0Y5NH)			
	5 (UNII: 1753WB2F1M)		
FD&C RED NO. 40 (U	JNII: WZB9127XOA)		
Product Charac	teristics		
Color	red	Score	
Shape		Size	
Flavor	STRAWBERRY	Imprint Code	
Contains			
Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:64522-003-	30 g in 1 JAR; Type 0: Not a Combin Product	ation 02/01/2018	
Marketing Ir	oformation		
Marketing	Application Number or Mo		Marketing End
Category	Citation	Date	Date
OTC monograph not final	part356	02/01/2018	

Labeler - Inter-Med, INC. (036623932)

Revised: 1/2022

Inter-Med, INC.