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).

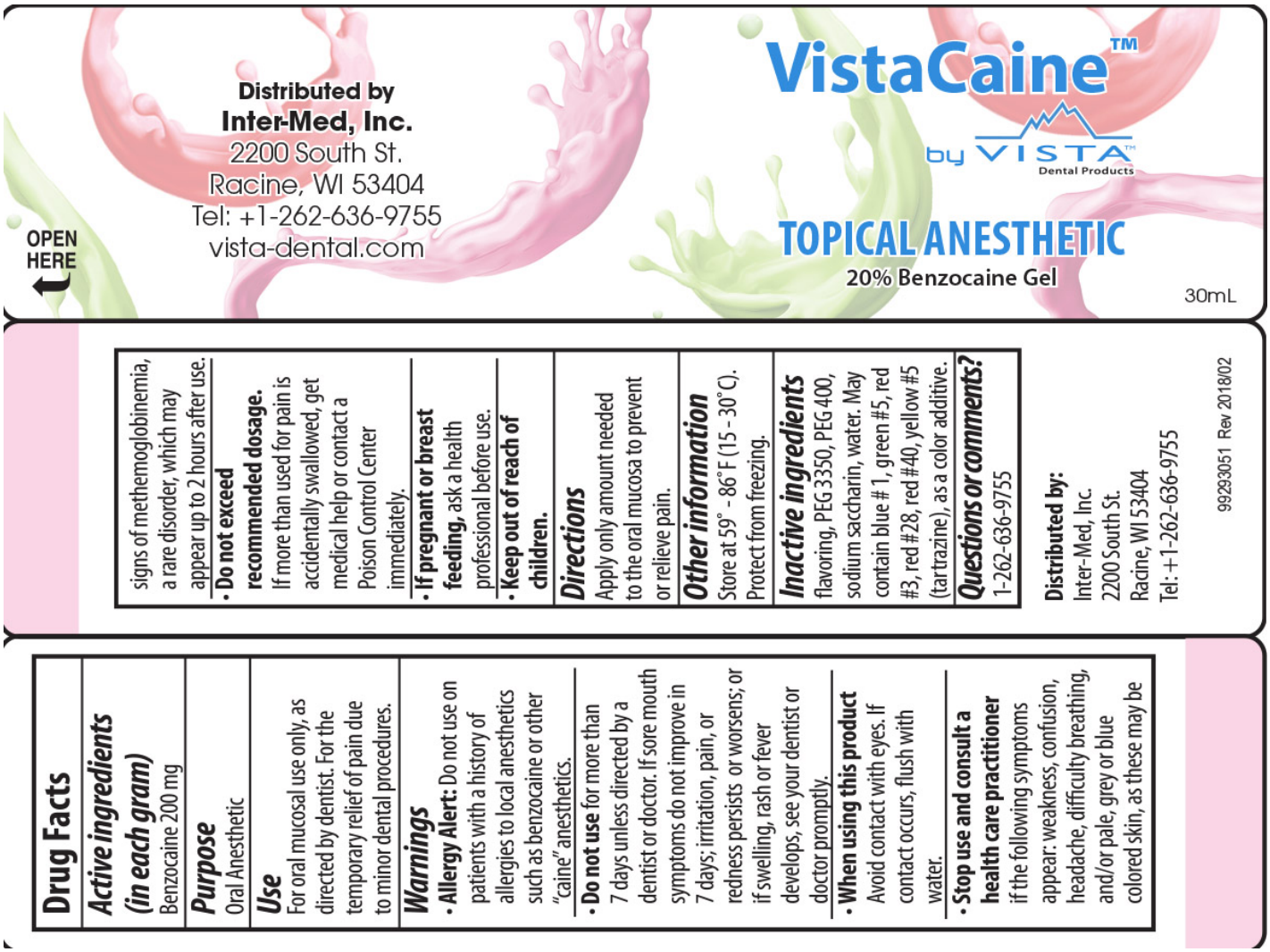
Protect from freezing.

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:64522-001
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
WATER (UNII: 059QF0KO0R)	
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)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Product Characteristics

Color	pink	**Score**	
Shape		**Size**	
Flavor	BUBBLE GUM	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64522-001-30	30 g in 1 JAR; Type 0: Not a Combination Product	02/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	02/01/2018	

Labeler - Inter-Med, INC. (036623932)

Revised: 1/2022 Inter-Med, INC.