PURELIFE TOPICAL ANESTHETIC- benzocaine gel PureLife Dental

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

Benzocaine 200mg (in each g)

Purpose

Oral Anesthetic

Use

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

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 the 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 heart rate
- shortness of breath
- dizziness or lightheadedness
- fatigue or lack of energy

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

Do not use

- for more than 7 days unless directed by a physician. 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 physician promptly.
- for teething
- in children under 2 years of age

When using this product Avoid contact with eyes. If contact occurs, flush with water.

Do not exceed recommended dosage. If more than used for pain is accidentally

swallowed, get medical help or contact a Poison Control Center right away. **If pregnant or breast feeding,** ask a physician before use.

Keep out of reach of children.

Directions

- Apply only amount needed to the oral mucosa to prevent or relieve pain.
- children under 2 years of age: do not use

Other Information

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

Inactive Ingredients

flavoring, PEG 3350, PEG 400, sodium saccharin. May contain blue #1, green #3, green #5, red #3, red #28, red #40, yellow #5, (tartrazine), yellow #6, as a color additive.

Questions or comments?

877-777-3303 or purelifedental.com

MANUFACTURED FOR PureLife, LLC., Carson, CA 90810 www.PureLifeDental.com 877-777-3303

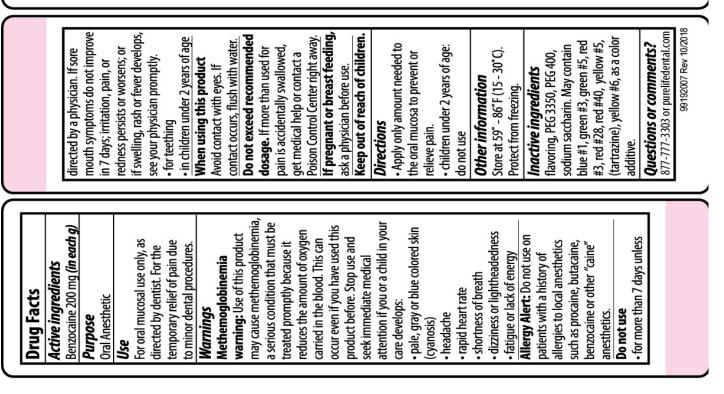
TOPICAL ANESTHETIC GEL Benzocaine 20%

PureLife.

Gluten Free

1oz (30ml)

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PURELIFE TOPICAL ANESTHETIC

benzocaine gel									
Product Information									
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:68987-003					
Route of Administration	DENTAL								
Active Ingredient/Active Moiety									
Ingredient Name Basis of Stre				gth	Strength				
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5) BEN			BENZOCAINE		200 mg in 1 g				
Inactive Ingredients									
Ingredient Name					Strength				
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)									
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)									
SACCHARIN SODIUM (UNII: SB8ZU	JX40TY)								

FD&C YELLOW NO.	5 (UNII: 1753WB2F1M)				
FD&C YELLOW NO.					
FD&C RED NO. 3 (UI	III: PN2ZH5LOQY)				
FD&C RED NO. 40 (JNII: WZ B9127XOA)				
FD&C BLUE NO. 1 (JNII: H3R47K3TBD)				
FD&C GREEN NO. 3	(UNII: 3P3ONR6O1S)				
D&C RED NO. 28 (UI	JII: 767IP0Y5NH)				
D&C GREEN NO. 5 (JNII: 8J6RDU8L9X)				
Product Charac	teristics				
Color	yellow		Score		
Shape			Size		
Flavor	PINEAPPLE (Pina Colada)		Imprint Code		
Contains					
Packaging					
# Item Code	Package Description	Mark	eting Start Date	Marketing Date	End
1 NDC:68987-003-	Package Description 30 g in 1 JAR; Type 0: Not a Combination Product	Mark 10/01/20	Date		End
1 NDC:68987-003-	30 g in 1 JAR; Type 0: Not a Combination		Date		End
1 NDC:68987-003-	30 g in 1 JAR; Type 0: Not a Combination Product		Date		End
1 NDC:68987-003- 30	30 g in 1 JAR; Type 0: Not a Combination Product	10/01/20	Date		
1 NDC:68987-003- 30 Marketing In Marketing	30 g in 1 JAR; Type 0: Not a Combination Product Iformation Application Number or Monograp	10/01/20 h Ma	Date 18 arketing Start	Date	

Labeler - PureLife Dental (828690904)

Revised: 1/2022

PureLife Dental