NRG TOPICAL ANESTHETIC- benzocaine gel IQ Dental Supply, LLC

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 mucosal use 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

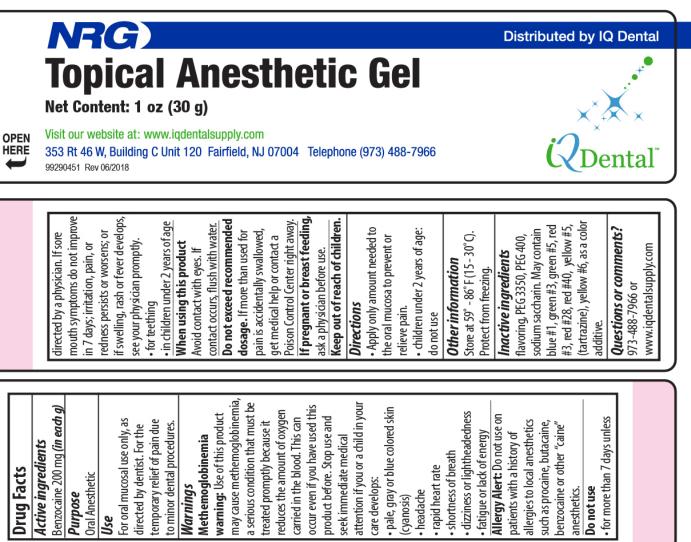
Store at 59° - 86°F (15°-30°C). Protect from freezing.

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 of comments?

973-488-7966 or www.iqdentalsupply.com



NRG TOPICAL	. ANEST	THETIC					
benzocaine gel							
Product Inform	ation						
Product Type		HUMAN OTC DRUG	ltem Co	em Code (Source)		NDC:42756-1106	
Route of Administ	ration	DENTAL					
Active Ingredier	nt/Active	Moiety					
Ingredient Name Basis of Stre						ngth Strength	
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5) BENZOCAINE					2	00 mg in 1 g	
Inactive Ingredi	ents						
Ingredient Name						Strength	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)							
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)							
SACCHARIN SODIUM (UNII: SB8ZUX40TY)							
FD&C YELLOW NO. 5	3 (UNII: 1753)	NB2F1M)					
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)							
FD&C RED NO. 3 (UN	II: PN2ZH5LO	DQY)					
FD&C RED NO. 40 (U	NII: WZ B912	7XOA)					
FD&C BLUE NO. 1 (U	NII: H3R47K3	STBD)					
FD&C GREEN NO. 3 (UNII: 3P3ON	R6O1S)					
D&C RED NO. 28 (UNII: 767IP0Y5NH)							
D&C GREEN NO. 5 (U	NII: 8J6RDU8	L9X)					
Product Charac	toristics						
			C				
Color red		Score Size					
Shape							
Flavor	STR	AWBERRY	Imp	rint Code			
Contains							
De else site s							
Packaging							
# Item Code		kage Description		larketing Start Date		eting End Date	
NDC:42756- 1106-3 30 g in 1 JAR; Type 0: Not a Combination Product 06/01/2018							
Marketing In	format	ion					
Marketing Category	Application Number or Monograph Citation			Marketing Start Date	rt Marketing End Date		
OTC monograph not	nort2E6			00/01/2012			

00/01/2013

Labeler - IQ Dental Supply, LLC (800349763)

Revised: 1/2022

IQ Dental Supply, LLC