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

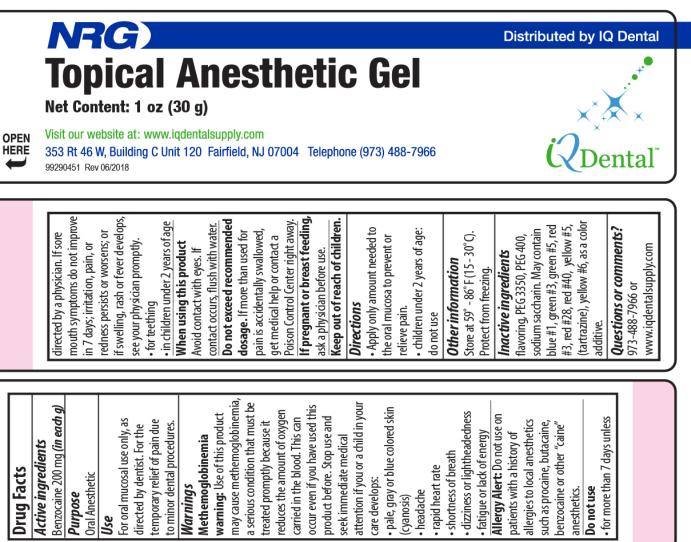
Store at 59° - 86°F (15°-30°C). Protect from freezing.

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



	L ANEST	HETIC					
penzocaine gel	- /						
Product Inform	-						
	ation						
Product Type		HUMAN OTC DRUG	Item Cod	e (Source)	NDC:42756-110	8	
Route of Administ	tration	DENTAL					
Active Ingredie	nt/Active	Moiety					
Ingredient Name Basis of Stre					ngth Strer	ngth	
BENZOCAINE (UNII: U	J3RSY48JW5)	(BENZOCAINE - UNII:U3RSY48JW5)		BENZOCAINE	200 mg	in 1 g	
Inactive Ingred	ients						
Ingredient Name					Strength		
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)							
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)							
SACCHARIN SODIUM	(UNII: SB8Z	UX40TY)					
FD&C YELLOW NO.	5 (UNII: 1753)	VB2F1M)					
FD&C YELLOW NO.	6 (UNII: H77V	EI93A8)					
D&C RED NO. 3 (UN	NII: PN2ZH5LC	DQY)					
FD&C RED NO. 40 (U	JNII: WZB912	7XOA)					
FD&C BLUE NO. 1 (U	JNII: H3R47K3	TBD)					
FD&C GREEN NO. 3	(UNII: 3P3ON	R6O1S)					
D&C RED NO. 28 (UI	NII: 7671P0Y5N	IH)					
D&C GREEN NO. 5 (JNII: 8J6RDU8	L9X)					
Product Charac	teristics						
Color		purple Score					
Shape		· · ·	ize				
Flavor			nprint Code	•			
Contains				•			
contains							
Packaging							
# Item Code	Pac	kage Description	Ma	rketing Start Date	Marketing Date	End	
	30 g in 1 JAR; Product	Type 0: Not a Combinatio	on 06/01	/2018			
	oformat	ion					
Marketing Ir	normat						
Marketing Ir Marketing Category		tion Number or Mone Citation	ograph	Marketing Start Date	Marketing Date	End	

00/01/2013

Labeler - IQ Dental Supply, LLC (800349763)

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IQ Dental Supply, LLC