TIGER SUPPLY INC TOPICAL ANESTHETIC- benzocaine gel Tiger Supply 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 Ingredient

Benzocaine 200mg (in each g)

Purpose

Oral Anesthetic

Use

For oral mucosa 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

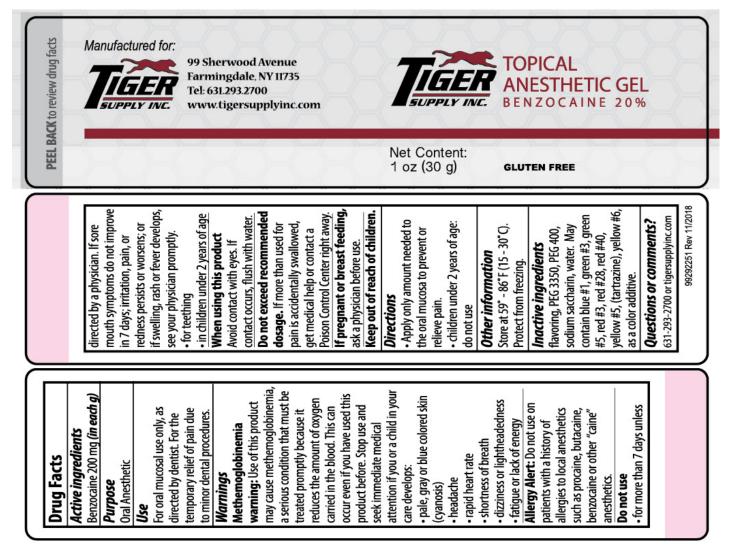
Store at 59° - 86°F (15°-30°C). Protect from freezing.

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 or comments?

631-293-2700 or www.tigersupplyinc.com



TIGER SUPPLY INC TOPICAL ANESTHETIC

benzocaine gel

benzocaine gel							
Product Inform	nation						
Product Type		HUMAN OTC DRUG	Iter	n Code	(Source)	NDC	69484-006
Route of Adminis	stration	DENTAL					
Active Ingredie	ent/Active	Moiety					
Ingredient Name Basis of Str						ength Strength	
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY							200 mg in 1 g
Inactive Ingred	dients						
Ingredient Name							Strength
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)							
POLYETHYLENE GL	YCOL 400 (UN	III: B697894SGQ)					
SACCHARIN SODIU	M (UNII: SB8ZL	JX40TY)					
FD&C YELLOW NO	5 (UNII: 1753W	B2F1M)					
FD&C YELLOW NO	. 6 (UNII: H77VE	EI93A8)					
FD&C RED NO. 3 (U							
FD&C RED NO. 40							
FD&C BLUE NO. 1	(UNII: H3R47K3	FBD)					
FD&C GREEN NO. 3							
D&C RED NO. 28 (U							
D&C GREEN NO. 5	(UNII: 8J6RDU8L	.9X)					
Product Chara	cteristics						
Color green			Score				
Shape			Size				
Flavor		MINT	Imprint Code				
Contains							
Packaging							
# Item Code	Package Description			Mar	Marketing Start Ma Date		keting End Date
1 NDC:69484-006- 30	30 g in 1 JAR; Type 0: Not a Combination Product			11/01/2018			
Marketing I	nformati	on					
Marketing Category	Applicat	Application Number or Monogra Citation			larketing Start Date	arketing End Date	
OTC monograph not final	part356			05/0	08/2013		

Labeler - Tiger Supply Inc. (168720709)

Revised: 1/2022

Tiger Supply Inc.