#### 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.

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#### **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**

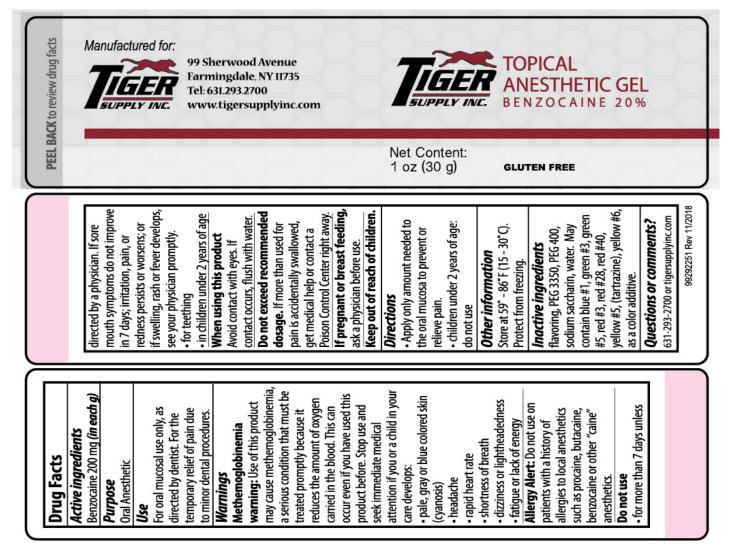
Store at 59° - 86°F (15°-30°C). Protect from freezing.

## **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	lter	n Code	(Source)	NDC	:69484-003	
Route of Adminis	stration	DENTAL						
Active Ingredie	ent/Active	Moiety						
Ingredient Name Basis o						Strength Strength		
BENZOCAINE (UNII:	-	(BENZOCAINE - UNII:U3RSY48JW5)			BENZOCAINE		 200 mg in 1 g	
Inactive Ingred	dients							
Ingredient Name							Strength	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)								
POLYETHYLENE GL	YCOL 400 (U	NII: B697894SGQ)						
SACCHARIN SODIU	<b>M</b> (UNII: SB8Z	UX40TY)						
FD&C YELLOW NO	<b>. 5</b> (UNII: 1753)	WB2F1M)						
FD&C YELLOW NO	. 6 (UNII: H77)	/EI93A8)						
FD&C RED NO. 3 (U								
FD&C RED NO. 40								
FD&C BLUE NO. 1	(UNII: H3R47K	3TBD)						
FD&C GREEN NO. 3								
D&C RED NO. 28 (U								
D&C GREEN NO. 5	(UNII: 8J6RDU8	BL9X)						
<b>Product Chara</b>	cteristics							
Color red			Score					
Shape			Size					
Flavor		CHERRY	Imprint Code					
Contains								
Packaging								
# Item Code	Package Description			Marl	Marketing Start Ma Date		rketing End Date	
<b>1</b> NDC:69484-003- 30	30 g in 1 JAR; Type 0: Not a Combination Product			11/01/2018				
Marketing I	nformat	ion						
Marketing Category	Application Number or Monogra Citation			n Marketing Start M Date			arketing End Date	
OTC monograph not	part356				08/2013			

# Labeler - Tiger Supply Inc. (168720709)

Revised: 1/2022

Tiger Supply Inc.