ASTRA-DENT TOPICAL ANESTHETIC GEL- benzocaine gel Zag Usa 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 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 or comments?

1-877-832-6963 or www.omnidentalsupply.com

Distributed by: Omni Dental Supply Brooklyn, NY 11232 (877) 832-6963

www.omnidentalsupply.com

99093651 Rev 08/2018



Topical Anesthetic Gel

Benzocaine 20%

Net Wt. 1 oz. (30 ml)



f swelling, rash or fever develops, mouth symptoms do not improve directed by a physician. If sore redness persists or worsens; or see your physician promptly. in 7 days; irritation, pain, or

If pregnant or breast feeding, in children under 2 years of age Do not exceed recommendec Poison Control Center right away contact occurs, flush with water. dosage. If more than used for pain is accidentally swallowed get medical help or contact a When using this product Avoid contact with eyes. If · for teething

(eep out of reach of children. Apply only amount needed to ask a physician before use. Directions

relieve pain.

 children under 2 years of age: the oral mucosa to prevent or Store at 59° - 86° F (15 - 30° Other information do not use

Inactive ingredients Protect from freezing.

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

Questions or comments? additive

877-832--6963 or

www.omnidentalsupply.com

Active ingredients **Drug Facts**

senzocaine 200 mg *(in each a*)

For oral mucosal use only, as emporary relief of pain due directed by dentist. For the Oral Anesthetic asoaun Se

to minor dental procedures Methemoglobinemia Warnings

may cause methemoglobinemia a serious condition that must be attention if you or a child in your occur even if you have used this reduces the amount of oxygen warning: Use of this product carried in the blood. This can product before. Stop use and treated promptly because it seek immediate medical

pale, gray or blue colored skin care develops: cyanosis

rapid heart rate headache

dizziness or lightheadedness fatigue or lack of energy shortness of breath

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

Do not use anesthetics.

for more than 7 days unless

ASTRA-DENT TOPICAL ANESTHETIC GEL

benzocaine gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:71363-107

Route of Administration DENTAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength **BENZ OCAINE** BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5) 200 mg in 1 g

Inactive Ingredients

Ingredient Name Strength POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P) POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)

SACCHARIN SODIUM (UNII: SB8ZUX40TY)

FD&C YELLOW NO. 6 (UNII: H77VEI93A8) FD&C RED NO. 3 (UNII: PN2ZH5LOQY) FD&C RED NO. 40 (UNII: WZB9127XOA) FD&C BLUE NO. 1 (UNII: H3R47K3TBD) FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S) D&C RED NO. 28 (UNII: 767IP0Y5NH) D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)	FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C RED NO. 40 (UNII: WZB9127XOA) FD&C BLUE NO. 1 (UNII: H3R47K3TBD) FD&C GREEN NO. 3 (UNII: 3P3ONR601S) D&C RED NO. 28 (UNII: 767IP0Y5NH)	FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD) FD&C GREEN NO. 3 (UNII: 3P3ONR601S) D&C RED NO. 28 (UNII: 767IP0Y5NH)	FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S) D&C RED NO. 28 (UNII: 767IP0Y5NH)	FD&C RED NO. 40 (UNII: WZB9127XOA)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
	FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)	D&C RED NO. 28 (UNII: 767IP0Y5NH)	
	D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)	

Product Characterist	roduct Characteristics			
Color	red	Score		
Shape		Size		
Flavor	STRAWBERRY	Imprint Code		
Contains				

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:71363-107- 30	28 g in 1 JAR; Type 0: Not a Combination Product	08/01/2018	

Marketing In	Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part356	07/01/2016			

Labeler - Zag Usa Inc (079487975)

Revised: 1/2022 Zag Usa Inc