MS TOPICAL ANESTHETIC- benzocaine gel M&S Dental Supply Co., 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.

Directions

- Apply only amount needed to the oral mucosa to prevent or relieve pain.
- children under 2 years of age: do not use

Keep out of reach of children.

Other Information

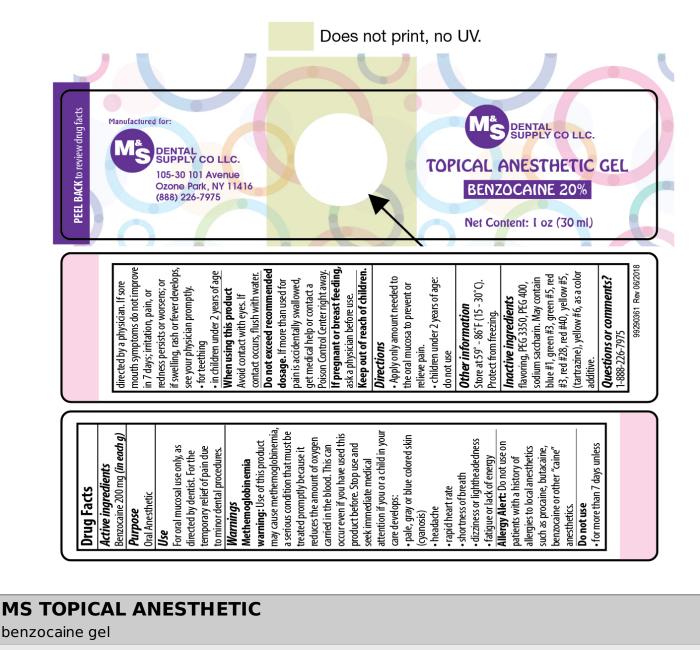
Store at 59°-86°F (15°-30°C). Protect from freezing.

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?

1-888-226-7975



Product Information					
Product Type	HUMAN OTC DRUG	ltem Code	(Source)	NDC	:69745-063
Route of Administration	DENTAL				
Active Ingredient/Active	Molety				
Ingredient Name Basis of Stren					Strength
BENZOCAINE (UNII: U3RSY48JW5)	BENZOCAINE		200 mg in 1 g		
Inactive Ingredients					
Inactive Ingredients	Ingredient Name				Strength
Inactive Ingredients POLYETHYLENE GLYCOL 3350 (I	-				Strength
-	JNII: G2M7P15E5P)				Strength

FD&C YELLOW NO.	5 (UNII: 1753WE	32F1M)						
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)								
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)								
FD&C RED NO. 40 (UNII: WZ B9127XOA)								
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)								
FD&C GREEN NO. 3 (UNII: 3P3ONR601S)								
D&C RED NO. 28 (UNII: 767IP0Y5NH)								
D&C GREEN NO. 5 (JNII: 8J6RDU8L9)X)						
Product Charac	teristics							
Color	green	Score						
Shape			Size					
Flavor		MINT	Imprint Code					
Contains								
Packaging								
# Item Code	Package Description		Ν	larketing Start Date	Marketing End Date			
	30 g in 1 JAR; T Product	ype 0: Not a Combir	ation	06/0	01/2018			
	-							
Marketing Information								
Marketing Category	Applicati	on Number or M Citation	onograpl	h	Marketing Start Date	Marketing End Date		
OTC monograph not final	part356				11/01/2014			

Labeler - M&S Dental Supply Co., LLC (173747767)

Revised: 1/2022

M&S Dental Supply Co., LLC