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

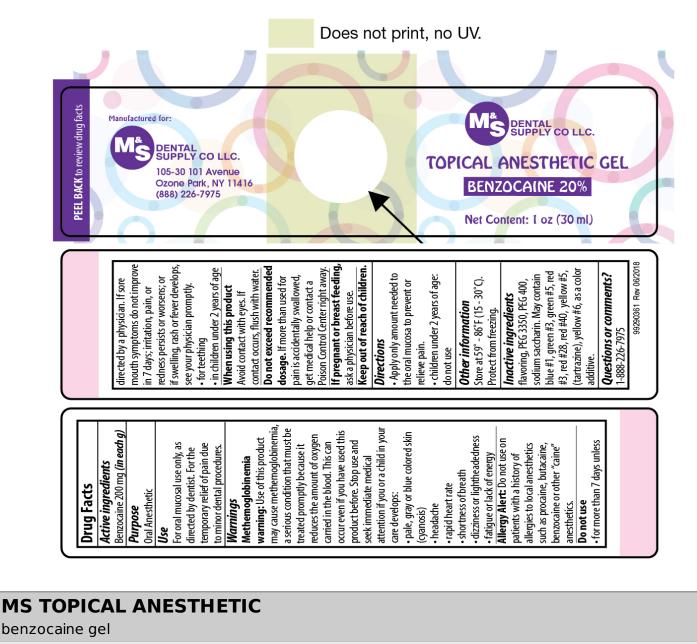
Store at 59°-86°F (15°-30°C). Protect from freezing.

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	Item Code	(Source)	NDC	:69745-066
Route of Administration	DENTAL				
	NA - 1 - 1				
Active Ingredient/Active	Molety				
Ingree	Basis of Strength		Strength		
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5) BENZOCAINE					200 mg in 1 g
Inactive Ingredients					
	Ingredient Name				Strength
	-				Strength
POLYETHYLENE GLYCOL 3350					
POLYETHYLENE GLYCOL 400 (U	INII: B697894SGQ)				

	- //	005114							
	FD&C YELLOW NO. 5 (UNII: I753WB2F1M)								
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: 8J6RDU8L	.9X)							
Product Charac	teristics								
Color		purple	Score						
Shape			Size						
Flavor GRAPE		Imprint Code							
Contains									
Packaging									
# Item Code	Pac	Package Description		Ν	larketing Start Date	Marketing End Date			
NDC:69745-066- 30 30 g in 1 JAR; Type 0: Not a Combination Product 06/01/2018									
	,	•							
Marketing Ir	ntormati	on							
Marketing Category	Applicat	Application Number or Monograp Citation		ו	Marketing Start Date	Marketing End Date			
OTC monograph not final	part356	part356			11/01/2014				

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

Revised: 1/2022

M&S Dental Supply Co., LLC