ZIP TOPICAL ANESTHETIC GEL MINT- benzocaine gel
Germiphene Corporation

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Zip Topical Anesthetic Gel Mint

Use or purpose:

For rapid topical anesthesia

Medicinal ingredient: Benzocaine 20.0% w/w

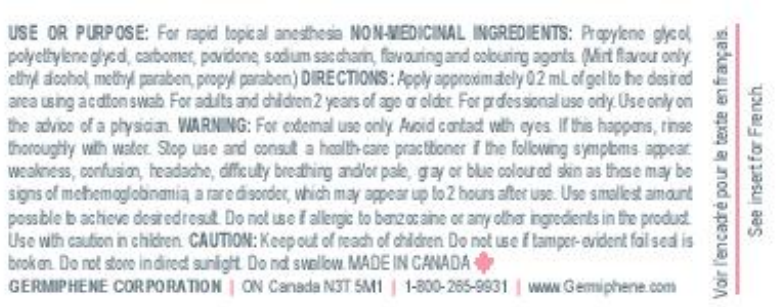
Topical Anesthetic Gel

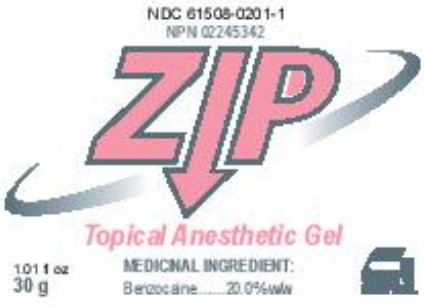
Non-Medicinal Ingredients: Propylene glycol, polyethylene glycol, carbomer, povidone, sodium saccharin, flavouring, and colouring agents. (Mint flavour only: ethyl alcohol, methyl paraben, propyl paraben).

Directions: Apply approximately 0.2 mL of gel to the desired area using a cotton swab. For adults and children 2 years of age or older. For professional use only. Use only on the advice of a physician.

Warning: For external use only. Avoid contact with eyes. If this happens, rinse thoroughly with water. Stop use and consult a health-care practitioner if the following symptoms appear: weakness, confusion, headache, dificulty breathing and/or pale, gray or blue coloured skin as these may be signs of methemoglobinemia, a rare disorder, which may appear up to 2 hours after use. Use smallest amount possible to achieve desired result. Do not use if allergic to benzocaine or any other ingredients in the product. Use with caution in children. Do not use if tamper-evident foil seal is broken. Do not store in direct sunlight. Do not swallow.

Caution: Keep out of reach of children.





ZIP TOPICAL ANESTHETIC GEL MINT

benzocaine gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61508-0201
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	20 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	0.565 g in 100 g
POVIDONE (UNII: FZ989GH94E)	0.248 g in 100 g
ALCOHOL (UNII: 3K9958V90M)	0.065 g in 100 g
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	0.0249 g in 100 g
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	0.00155 g in 100 g
METHYLPARABEN (UNII: A2I8C7HI9T)	0.00016 g in 100 g
PROPYLPARABEN (UNII: Z8IX2SC1OH)	0.00016 g in 100 g
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	0.697 g in 100 g
CARBOMER 934 (UNII: Z135WT9208)	3.086 g in 100 g
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	43.29 g in 100 g
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	30.62 g in 100 g

Product Characteristics

Color	green	**Score**	
Shape		**Size**	
Flavor	MINT	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61508-0201-1	30 g in 1 JAR; Type 0: Not a Combination Product	06/16/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/16/2017	

Labeler - Germiphene Corporation (206412512)

Establishment

Name	Address	ID/FEI	Business Operations
Germiphene Corporation		206412512	manufacture(61508-0201)

Revised: 6/2017 Germiphene Corporation