

**ZIP TOPICAL ANESTHETIC GEL STRAWBERRY- 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 Strawberry**

For rapid topical anesthesia

For rapid topical anesthesia

Medicinal Ingredients: Benzocaine 20% w/w

Propylene glycol, polyethylene glycol, carbomer, povidone, sodium saccharin, flavouring and colouring agents. (mint flavour only: ethyl alcohol, methyl paraben, propyl paraben.)

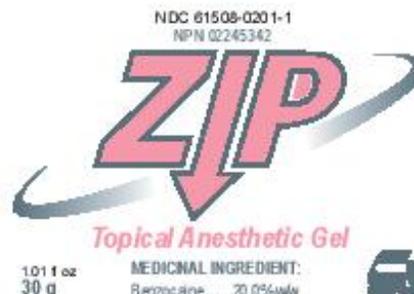
Directions: Apply approximately 0.2 mL of gel to the desired area using a cotton swab. For adults and children 2 years of age or older. For professional use only. Use only on the advice of a physician.

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, difficulty 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.

Keep out of reach of children.

**USE OR PURPOSE:** For rapid topical anesthesia **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, difficulty 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. **CAUTION:** Keep out of reach of children. Do not use if tamper-evident foil seal is broken. Do not store in direct sunlight. Do not swallow. **MADE IN CANADA**   
 GERMIPHENE CORPORATION | ON Canada N3T 5M1 | 1-800-265-9931 | www.Germiphene.com

Voir l'encadré pour le texte en français.  
 See inset for French.



**ZIP TOPICAL ANESTHETIC GEL STRAWBERRY**

benzocaine gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61508-0202
<b>Route of Administration</b>	DENTAL		

**Active Ingredient/Active Moiety**

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

## Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	0.002 g in 100 g
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	43.7 g in 100 g
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	30.75 g in 100 g
POVIDONE (UNII: FZ989GH94E)	0.25 g in 100 g
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	0.7 g in 100 g
CARBOMER 934 (UNII: Z135WT9208)	3.1 g in 100 g

## Product Characteristics

Color	red	Score	
Shape		Size	
Flavor	STRAWBERRY	Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61508-0202-1	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(61508-0202)

Revised: 6/2017

Germiphene Corporation