

## **SCOTTS SELECT TOPICAL ANESTHETIC- benzocaine gel**

**Scott's Dental Supply 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.*

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### **Scott's Select Topical Anesthetic Gel**

#### **Drug Facts**

#### **Active Ingredients**

Benzocaine, 20%

#### **Purpose**

Oral Anesthetic

#### **Uses**

For the temporary relief of pain associated with canker sores and minor dental procedures.

#### **Warnings**

##### **Allergy Alert**

Do Not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine, or other "-caine" anesthetics.

**Do not use** this product for more than 7 days unless directed by a dentist or doctor. If sore mouth symptoms do not improve in 7 days; if irritation, pain, or redness persists or worsens; or if swelling, rash or fever develops, see your dentist or doctor promptly.

**Do not** exceed recommended dosage.

**Keep out of reach of children. If more than used for pain is accidentally swallowed, get medical help or contact a Poison Control Center right away.**

#### **Directions**

- Adults and children 12 years of age and older: Apply to the affected area. Use up to 4 times daily or as directed by a dentist or doctor.
- Children under 12 years of age should be supervised in the use of this product.
- Children under 2 years of age: Consult a dentist or doctor.

#### **Other Information**

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

#### **Inactive Ingredients**

FD&C Red # 40, Flavor, Polyethylene glycol 3350, Polyethylene glycol 400, Saccharine sodium, Tocopheryl acetate, Xylitol.

# PRINCIPAL DISPLAY PANEL - 32 g Bottle Label

Scott's  
SELECT

TOPICAL ANESTHETIC GEL  
With Vitamin E and Xylitol • Gluten Free

REORDER 972-4405

1.12 OZ (32g)

BUBBLE GUM

Peel Here



<p><b>Warnings</b>  <b>Allergy Alert</b> Do Not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine, or other "-caine" anesthetics.  <b>Do not use</b> this product for more than 7 days unless directed by a dentist or doctor. If sore mouth symptoms do not improve in 7 days; if irritation, pain, or redness persists or worsens; or if swelling, rash or fever develops, see your dentist or doctor promptly.  <b>Do not exceed</b> recommended dosage.  <b>Keep out of reach of children. If more than used for pain is accidentally swallowed, get medical help or contact a Poison Control Center right away.</b></p>	<p><b>Directions</b>          • Adults and children 12 years of age and older: Apply to the affected area. Use up to 4 times daily or as directed by a dentist or doctor.          • Children under 12 years of age should be supervised in the use of this product.          • Children under 2 years of age: Consult a dentist or doctor.  <b>Other Information</b>          Store at room temperature 59 - 86 °F (15 - 30 °C). Protect from freezing and heat.  <b>Inactive Ingredients</b>          FD&amp;C Red # 40, Flavor, Polyethylene glycol 3350, Polyethylene glycol 400, Saccharine sodium, Tocopheryl acetate, Xylitol.</p>
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<p>Manufactured for:  <b>Scott's Dental Supply</b> 1-800-901-3368          7217 45th Street CT E          Ste 103, Fife, WA 98424          www.ScottsDental.com</p> <p><b>Drug Facts</b></p> <table border="1"> <tr> <th>Active Ingredients</th> <th>Purpose</th> </tr> <tr> <td>Benzocaine, 20%.....Oral Anesthetic</td> <td></td> </tr> </table> <p><b>Uses</b>          For the temporary relief of pain associated with canker sores and minor dental procedures.</p>	Active Ingredients	Purpose	Benzocaine, 20%.....Oral Anesthetic		<p>Manufactured for:  <b>Scott's Dental Supply</b> Made in USA          7217 45th Street CT E          Ste 103, Fife, WA 98424          www.SCOTSDENTAL.com 1-800-901-3368</p>
Active Ingredients	Purpose				
Benzocaine, 20%.....Oral Anesthetic					

## SCOTT'S SELECT TOPICAL ANESTHETIC benzocaine gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69638-060
Route of Administration	ORAL, 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
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>POLYETHYLENE GLYCOL 3350</b> (UNII: G2M7P15E5P)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	

**Product Characteristics**

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BUBBLE GUM	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69638-060-32	32 g in 1 BOTTLE; Type 0: Not a Combination Product	07/23/2017	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part356	07/23/2017	

**Labeler** - Scott's Dental Supply LLC (137217043)