#### SCOTTS SELECT TOPICAL ANESTHETIC- benzocaine gel

Scott's Dental Supply LLC

Reference Label Set Id: 96e6a5de-7616-44fb-9d78-18968b7e3ee1 Reference Label Set Id: 341c856f-1519-4165-a7fd-4323794012bc Reference Label Set Id: b42f0d67-6777-42e4-99f8-94d84b409f55 Reference Label Set Id: 933f02a8-aaab-4e7e-945f-644c476ece78 Reference Label Set Id: 6a2c43ec-eb64-4fef-be2c-0294f8b8362e

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

MINT 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 Green #3, FD&C Yellow #5, Flavor, Polyethylene glycol 3350, Polyethylene glycol 400, Saccharine sodium, Tocopheryl acetate, Xylitol.

## CHERRY Drug Facts

#### **Active Ingredients**

Benzocaine, 20%

#### **Purpose**

Oral Anesthetic

#### Uses

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

## 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 the 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.

## STRAWBERRY Drug Facts

#### **Active Ingredients**

Benzocaine, 20%

#### **Purpose**

Oral Anesthetic

#### Uses

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

#### 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.

## PINA COLADA 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, FD&C Blue # 1, FD&C Yellow # 6, FD&C Yellow # 5, Flavor, Polyethylene glycol 3350, Polyethylene glycol 400, Saccharine sodium, Tocopheryl acetate, Xylitol.

## BUBBLE GUM 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.

# RASPBERRY 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, FD&C Blue # 1, Flavor, Polyethylene glycol 3350, Polyethylene glycol 400, Saccharine sodium, Tocopheryl acetate, Xylitol.

## PRINCIPAL DISPLAY PANEL - 32 g Bottle Label - MINT

Scott's SELECT ✓

TOPICAL ANESTHETIC GEL With Vitamin E and Xylitol • Gluten Free

**REORDER 972-4402** 

1.12 OZ (32g)

MINT



Manufactured for



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supervised in the use of years of age should be

 Adults and children 12 years of age and older:
 Apply to the affected daily or as directed by a area. Use up to 4 times Children under 12 dentist or doctor

temperature 59 - 86 °F (15 - 30 °C). Protect from freezing and heat. Children under 2 years of age: Consult a Other Information Store at room dentist or doctor

93-00110 Revision - 2/3/2022

oxygen carried in the blood. This can occur

reduces the amount of

Inactive Ingredients FD&C Red #10, Flavor, Polyethylene glycol 3350, Tocopheryl acetate, Xylitol. Polyethylene glycol 400, Saccharine sodium,

a child in your case medical attention if you or thus product before. Stop

use and seek immediate even if you have used

blue colored skin developes: • pale, gray, or

#### Drug Facts

Active Ingredients Purpose Benzocaine, 20%. Oral Anesthetic

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

Warnings continued on inside panel

or lack of energy. lightheadedness • fatigue shortness of breath • (cyanosis) • headache • rapid heart rate •

dizziness or

this product.

such as procaine, you have a history of allergy to local anesthetics Allergy Alert

Do Not use this product if other "-caine" anesthetics. butacaine, benzocaine, or

# Warnings

promptly because it that must be treated emia, a serious condition cause methemoglobin-Use of this product may Methemogloblinemia Warning:

recommended dosage.

Do not exceed

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

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

# PRINCIPAL DISPLAY PANEL - 32 g Bottle Label - CHERRY

Scott's SELECT ✓

TOPICAL ANESTHETIC GEL With Vitamin E and Xylitol • Gluten Free

**REORDER 972-4401** 

1.12 OZ (32g)

**CHERRY** 



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Directions

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years of age should be Children under 12

years of age and older:
Apply to the affected
area. Use up to 4 times
daily or as directed by a Adults and children 12 dentist or doctor.

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

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

#### Drug Facts

Active Ingredients Purpose Benzocaine, 20%. Oral Anesthetic

93-00110 Revision - 2/3/2022

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

Warnings continued on inside panel

Allergy Alert

or lack of energy

lightheadedness • fatigue

dizziness or

supervised in the use of

Children under 2 years

this product.

of age: Consult a

dentist or doctor.

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

shortness of breath • medical attention if you or even if you have used oxygen carried in the rapid heart rate • (cyanosis) • headache • blue colored skin developes: • pale, gray, or a child in your case use and seek immediate thus product before. Stop blood. This can occur reduces the amount of promptly because it that must be treated emia, a serious condition cause methemoglobin-Use of this product may Warning: Methemogloblinemia

away.

Control Center right contact a Poison

get medical help or

Warnings

accidentally swallowed, Keep out of reach of children. If more than used for pain is recommended dosage. Do not exceed or doctor promptly. Do not use this product for more than 7 days develops, see your dentist swelling, rash or fever persists or worsens; or if irritation, pain, or redness improve in 7 days; if dentist or doctor. If sore unless directed by a mouth symptoms do not

# PRINCIPAL DISPLAY PANEL - 32 g Bottle Label - STRAWBERRY

Scott's SELECT ✓

TOPICAL ANESTHETIC GEL With Vitamin E and Xylitol • Gluten Free

**REORDER 972-4403** 

1.12 OZ (32g)

**STRAWBERRY** 



Manufactured for



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area. Use up to 4 times daily or as directed by a

years of age and older. Apply to the affected Adults and children 12

Children under 2 years of age: Consult a dentist or doctor.

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

> blue colored skin a child in your case medical attention if you or thus product before. Stop

rapid heart rate • (cyanosis) • headache • developes: • pale, gray, or

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

Inactive Ingredients

even if you have used

use and seek immediate

blood. This can occur oxygen carried in the 93-00110 Revision - 2/3/2022

## Drug Facts

Active Ingredients Benzocaine, 20% ... Oral Anesthetic

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

Warnings continued on inside panel

Do Not use this product if Allergy Alert

years of age should be supervised in the use of

this product.

or lack of energy.

lightheadedness · fatigue

dizziness or shortness of breath •

Children under 12

denfist or doctor.

butacaine, benzocaine, or such as procaine, you have a history of other "-caine" anesthetics allergy to local anesthetics

# Warnings

recommended dosage.

Do not exceed

reduces the amount of promptly because it that must be treated emia, a serious condition cause methemoglobin-Use of this product may Warning: Methemogloblinemia

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

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

# PRINCIPAL DISPLAY PANEL - 32 g Bottle Label - PINA COLADA

Scott's SELECT ✓ TOPICAL ANESTHETIC GEL

With Vitamin E and Xylitol • Gluten Free

**REORDER 972-4404** 

1.12 OZ (32g)

PIÑA COLADA



Manufactured for



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of age: Consult a

this product.

dentist or doctor.

(cyanosis) · headache ·

blue colored skin

rapid heart rate •



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supervised in the use of Children under 2 years years of age should be

daily or as directed by a area. Use up to 4 times Adults and children 12 years of age and older. Apply to the affected Children under 12 dentist or doctor. Directions

Tocopheryl acetate, Xylitol. Polyethylene glycol 400, Saccharine sodium,

oxygen carried in the

blood. This can occur reduces the amount of

promptly because it that must be treated emia, a serious condition

93-00110 Revision - 2/3/2022

Store at room temperature 59 - 86 °F (15 - 30 °C) Protect from freezing and heat. FD&C Red #40, Flavor, Polyethylene glycol 3350 hactive Ingredients Other Information

a child in your case

developes: • pale, gray, or medical attention if you or use and seek immediate thus product before. Stop even if you have used

#### Drug Facts

Purpose Active Ingredients Benzocaine, 20% Oral Anesthetic

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

Warnings continued on inside panel

# Allergy Alert

or lack of energy.

ightheadedness · fatigue

dizziness or shortness of breath •

butacaine, benzocaine, allergy to local anesthetics you have a history of Do Not use this product if other "-caine" anesthetics. such as procaine, 2

cause methemoglobin-Use of this product may Warning: Methemogloblinemia

> recommended dosage. Do not exceed

Warnings

away. accidentally swallowed, used for pain is children. If more than Control Center right contact a Poison get medical help or Keep out of reach of or doctor promptly. swelling, rash or fever irritation, pain, or redness mouth symptoms do not improve in 7 days; if unless directed by a Do not use this product for more than 7 days develops, see your dentist persists or worsens; or if dentist or doctor. If sore

# PRINCIPAL DISPLAY PANEL - 32 g Bottle Label - BUBBLE GUM

Scott's SELECT ✓

TOPICAL ANESTHETIC GEL With Vitamin E and Xylitol • Gluten Free

**REORDER 972-4405** 

1.12 OZ (32g)

**BUBBLE GUM** 



Manufactured for



Directions

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Adults and children 12

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

Store at room temperature 59 - 86 °F (15 - 30 °C). Protect from freezing and heat. of age: Consult a dentist or doctor.

rapid heart rate •

(cyanosis) · headache · blue colored skin developes: • pale, gray, or a child in your case medical attention if you or thus product before. Stop even if you have used blood. This can occur oxygen carried in the Drug Facts

Active Ingredients Purpose Benzocaine, 20%. Oral Anesthetic

Uses

93-00110 Revision - 2/3/2022

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

Warnings continued on inside panel

ocopheryl acetate, Xylitol. Polyethylene glycol 3350 Polyethylene glycol 400, FD&C Red #10, Flavor nactive Ingredients Saccharine sodium, Other Information

use and seek immediate

Allergy Alert

or lack of energy.

lightheadedness • fatigue

dizziness or shortness of breath •

Children under 2 years

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

# Warnings

Warning: emia, a serious condition cause methemoglobin-Methemogloblinemia Jse of this product may

> recommended dosage. Do not exceed

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

promptly because it

reduces the amount of that must be treated

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

## PRINCIPAL DISPLAY PANEL - 32 g Bottle Label - RASPBERRY

Scott's SELECT ✓

TOPICAL ANESTHETIC GEL With Vitamin E and Xylitol • Gluten Free

**REORDER 972-4406** 

1.12 OZ (32g)

**RASPBERRY** 



Manufactured for



7217 45th St Ct E #103, Fife, WA 98424 (800)901-3368 SCAL ANESTHETIC

SCOTTSDENTAL,COM

temperature 59 - 86 °F (15 - 30 °C). Protect from freezing and heat. supervised in the use of Children under 2 years of age: Consult a Other Information Store at room dentist or doctor. this product.

rapid heart rate •

93-00110 Revision - 2/3/2022

ocopheryl acetate, Xylitol

Polyethylene glycol 3350

FD&C Red #40, Flavor,

Inactive Ingredients

a child in your case

Polyethylene glycol 400, Saccharine sodium,

Active Ingredients Uses

procedures

Benzocaine, 20% .. Oral Anesthetic

Purpose

**Drug Facts** 

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

Warnings continued on inside panel

Allergy Alert

or lack of energy.

lightheadedness • fatigue

dizziness or shortness of breath • (cyanosis) · headache · blue colored skin developes: • pale, gray, or medical attention if you or

years of age should be

Children under 12

dentist or doctor.

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

area. Use up to 4 times daily or as directed by a

years of age and older. Apply to the affected

Adults and children 12

Directions

# Warnings

recommended dosage.

Do not exceed

oxygen carried in the use and seek immediate thus product before. Stop even if you have used blood. This can occur reduces the amount of promptly because it that must be treated emia, a serious condition cause methemoglobin-Use of this product may Warning: Methemogloblinemia

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

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

## SCOTTS SELECT TOPICAL ANESTHETIC

benzocaine gel

<b>Product</b>	Intorm	ation

Product Type HUMAN OTC DRUG Item Code (Source) NDC:69638-063

**Route of Administration** ORAL, DENTAL

#### **Active Ingredient/Active Moiety**

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

## **Inactive Ingredients**

Ingredient Name	Strength
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
XYLITOL (UNII: VCQ006KQ1E)	

#### **Product Characteristics**

r roduct Characteristics		
Color		Score
Shape		Size
Flavor	MINT	Imprint Code
Contains		

#### **Packaging**

# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:69638-063-	32 g in 1 BOTTLE; Type 0: Not a Combination Product	07/20/2017	

# **Marketing Information**

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC monograph not final	part356	07/20/2017	

# **SCOTTS SELECT TOPICAL ANESTHETIC**

benzocaine gel

<b>Product</b>	Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69638-061
Product Type	HOMAN OTC DIVOG	item code (Source)	NDC.03030-001

**Route of Administration** ORAL, DENTAL

## **Active Ingredient/Active Moiety**

recite ingredient, recite i loiety		
Ingredient Name	<b>Basis of Strength</b>	Strength
Benzocaine (UNII: U3RSY48JW5) (Benzocaine - UNII:U3RSY48JW5)	Benzocaine	20 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics				
Color		Score		
Shape		Size		
Flavor	CHERRY	Imprint Code		
Contains				

l	P	Packaging			
	# Item Code Package Description		Marketing Start Date	Marketing End Date	
	1	NDC:69638-061- 32	32 g in 1 BOTTLE; Type 0: Not a Combination Product	07/23/2017	

Marketing Information			
Marketing Category Application Number or Monograph Marketing Start Marketing Citation Date Date			
OTC MONOGRAPH NOT FINAL	part356	07/23/2017	
1110			

# **SCOTTS SELECT TOPICAL ANESTHETIC**

## benzocaine gel

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:69638-065

**Route of Administration** ORAL, DENTAL

## **Active Ingredient/Active Moiety**

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

Inactive Ingredients	
Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics				
Color				
Shape		Size		
Flavor	STRAWBERRY	Imprint Code		
Contains				

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
NDC:69638-065-	32 g in 1 BOTTLE; Type 0: Not a Combination Product	07/23/2017		

Marketing Information  Marketing Category Application Number or Monograph Citation Date Date  Marketing Start Date			
FINAL			

# **SCOTTS SELECT TOPICAL ANESTHETIC**

benzocaine gel

# **Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69638-062
Route of Administration	ORAL, DENTAL		

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

Inactive Ingredients		
Ingredient Name	Strength	
FD&C RED NO. 40 (UNII: WZB9127XOA)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)		
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)		
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)		
XYLITOL (UNII: VCQ006KQ1E)		

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	PINEAPPLE (PINA COLADA)	Imprint Code	
Contains			

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:69638-062- 32	32 g in 1 BOTTLE; Type 0: Not a Combination Product	07/23/2017	

Marketing Information			
Marketing Category	Marketing End Date		
OTC MONOGRAPH NOT FINAL	part356	07/23/2017	

# **SCOTTS 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		
Benzocaine (UNII: U3RSY48JW5) (Benzocaine - UNII:U3RSY48JW5)	Benzocaine	20 g in 100 g		

Inactive Ingredients	
Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics			
Color			
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	
Contains			

l	P	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 Marketing Sta			Marketing End Date
OTC MONOGRAPH NOT FINAL	part356	07/23/2017	

# **SCOTTS SELECT TOPICAL ANESTHETIC**

benzocaine gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69638-064	
Route of Administration	ORAL, 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
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics				
Color				
Shape		Size		
Flavor	RASPBERRY	Imprint Code		
Contains				

l	P	Packaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:69638-064- 32	32 g in 1 BOTTLE; Type 0: Not a Combination Product	07/23/2017	

Marketing Information			
Marketing Category	Marketing End Date		
OTC monograph not final	part356	07/23/2017	

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

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