

## **ORAL GEL ORAL PAIN RELIEF- benzocaine benzalkonium chloride gel** **Savvy Care and Cosmetics**

*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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**Oral gel**

### **Active Ingredient**

Benzocaine 20%

Benzalkonium Chloride 0.1%

### **Purpose**

Oral pain reliever

Antiseptic

### **Use**

■ for the temporary relief of pain due to toothaches ■ to help protect against infection in minor oral irritation

### **Warnings**

■ **Allergy alert:** do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine or other "caine" anesthetics

### **Do not use**

■ more than directed ■ for more than 7 days unless directed by a physician or healthcare provider

### **Stop use and ask a physician if**

■ swelling, rash or fever develops ■ irritation, pain or redness persists or worsens ■ symptoms do not improve in 7 days

### **Keep out of reach of children**

In case of overdose or allergic reaction get medical help or contact a Poison Control Center right away

## Directions

■ adults and children 2 years of age and over: apply a small amount of the product to the cavity and around the gum surrounding the teeth Use up to 4 times daily or as directed by a physician or healthcare provider ■ children under 12 years: should be supervised in the use of this product ■ children under 2 years of age: ask a physician or health care provider

## Other information

■ this preparation is intended for use in cases of toothache, only as a temporary expedient until a physician can be consulted ■ do not use continuously ■ avoid using toothpaste or drinking soft drinks or fruit juices for at least one hour after applying ■ do not use if tube seal under cap is broken, missing or if the tube tip is cut prior to opening

## Inactive ingredients

ammonium glycyrrhizate, flavor, polyethylene glycol, sodium saccharin, sorbic acid

## Package Label



**Lucky Super Soft**

**NEW FORMULA!**

**Oral Pain Relief Gel**  
for **TOOTHACHE**

**MAXIMUM STRENGTH**

Net Wt. 0.5 oz. (14g)

Compare to Maximum Strength Orajel® Gel Active Ingredient\*

**INSTANT TOOTHACHE RELIEF**

**FAST-ACTING GEL**

### Drug Facts

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Benzalkonium Chloride 0.1% ..... Antiseptic

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### Drug Facts (continued)

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\*This product is not manufactured or distributed by Church & Dwight Co., Inc., owner of the registered trademark Orajel®.

Specially Manufactured for DELTA BRANDS INC., Larchmont, NY 10538 www.deltabrands.com ITEM NO: 10373 / MADE IN INDIA 10373/01(007)

## ORAL GEL ORAL PAIN RELIEF

benzocaine benzalkonium chloride gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83650-101
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>BENZOCAINE</b> (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	20 g in 100 g
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.1 g in 100 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>AMMONIUM GLYCYRRHIZATE</b> (UNII: 3VRD35U26C)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SORBIC ACID</b> (UNII: X045WJ989B)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:83650-101-01	42.5 g in 1 TUBE; Type 0: Not a Combination Product	09/22/2023	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part356	09/22/2023	

**Labeler -** Savvy Care and Cosmetics (915039748)

## Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Savvy Care and Cosmetics		915039748	manufacture(83650-101)

Revised: 9/2023

Savvy Care and Cosmetics