

## **MOUTH SORE RELIEF APPLICATOR- benzocaine liquid**

**Swabplus Inc.**

*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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### **Mouth Sore Relief Applicator**

#### **Drug fact**

Active Ingredient

Benzocaine 20%

#### **Purpose**

Pain Reliever

#### **Uses**

temporarily relieves these symptoms. cold sores. scanker sores. fever blisters. minor irritation or injury of the mouth and gums.

#### **Warning 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.

#### **When using this product**

avoid eye contact. do not exceed recommended dosage. do not use more than 7 days unless told to do so by a dentist or doctor.

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

swelling. rash or fever develops, irritation, pain, or redness persists or worsen.

Do not use on children under 2 years except under the advice and supervision of a doctor.

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

if swallowed get medical help or contact a Poison Control Center right away.

#### **Directions**

Snap the tip at the color ring. Allow formula to flow down to the opposite tip. Apply formula with the saturated tip to affected area

#### **Other Information**

Avoid storing at excessive heat.

## Inactive Ingredient

Polyethylene glycol 400 (PEG-8), Glycerin, Saccharin sodium, water, pina Colada

Image of carton label



**Mouth Sore Relief** Soft cotton tip applicators individually filled with Pain Reliever 73134400

<b>Drug Facts</b>	
<b>Active Ingredient</b>	<b>Purpose</b>
Benzocaine 20%	Pain Reliever
<b>Uses</b> • temporarily relieves these symptoms: • cold sores • canker sores • fever blisters • minor irritation or injury of the mouth and gums	
<b>Warnings 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>When using this product</b> • avoid eye contact • do not exceed recommended dosage • do not use for more than 7 days unless told to do so by a dentist or doctor	
<b>Stop use and ask a doctor if</b> • swelling, rash or fever develops • irritation, pain, or redness persists or worsens	
Do not use on children under 2 years of age except under the advice and supervision of a doctor. <b>Keep out of the reach of children.</b> If swallowed get medical help or contact a poison control center right away.	
<b>Directions</b> • Snap the tip at the color ring • Allow formula to flow down to the opposite tip • Apply formula with the saturated tip to affected area	
<b>Other Information</b> • Avoid storing at excessive heat	
<b>Inactive Ingredients</b> Diazolidinyl Urea, Ethoxydiglycol, Methylparaben, PEG-8, Pina Colada Flavor, Propylene Glycol, Propylparaben	
Patented and manufactured by Swabplus Inc. Rancho Cucamonga, CA 91730 USA. Made in USA. The COLOR RING is copyrighted by Swabplus Inc. ©2006 Swabplus Inc. www.swabplus.com	
Blue Formula Shows On The Package Is For Illustration Only. See Inside for More Details ▶	



## MOUTH SORE RELIEF APPLICATOR

benzocaine liquid

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:65734-867

<b>Route of Administration</b>	ORAL			
<b>Active Ingredient/Active Moiety</b>				
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>	
	BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	200 mg in 1 mL	
<b>Inactive Ingredients</b>				
	<b>Ingredient Name</b>	<b>Strength</b>		
	POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)			
	GLYCERIN (UNII: PDC6A3C0OX)			
	SACCHARIN SODIUM (UNII: SB8ZUX40TY)			
	WATER (UNII: 059QF0KO0R)			
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:65734-867-24	3.6 mL in 1 PACKET		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
OTC monograph final	part333B	06/01/2005		

**Labeler** - Swabplus Inc. (876441549)

**Registrant** - Swabplus Inc. (876441549)

### Establishment

Name	Address	ID/FEI	Business Operations
Swabplus Inc.		876441549	manufacture(65734-867) , relabel(65734-867) , repack(65734-867)

Revised: 2/2013

Swabplus Inc.