

## **DENTAL RELIEF- benzocaine liquid**

### **Cintas First Aid & Safety**

*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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### **Drug Facts**

Dental Relief

### **Active Ingredients**

Benzocaine 20% (w/w)

### **Purpose**

Oral antiseptic

### **Uses**

For temporary relief of minor pain and sore mouth associated with toothache, minor dental procedures and irritations from dentures or orthodontic appliances.

### **Warnings**

**For oral use only**

### **Allergy alert**

Do not use this product if you have a history of allergy to local anaesthetics, such as procaine, butacaine, benzocaine, or other "caine" anaesthetics due to the possibility of anaphylactic shock.

### **When using this product**

Do not use 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, fever or other allergic reaction develops, see your doctor or dentist promptly. Do not exceed recommended dosage.

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

If more than used for pain relief and protection is accidentally swallowed, get medical help or contact a Poison Control Center right away.

### **Directions**

- Adults and children 2 years and older: dry affected area and apply medication undiluted; Use up to 4 times daily, but not more than every two hours, or as directed by a dentist or doctor
- Consult a dentist or doctor for use on children under 2 years of age
- Children under 12 years of should be supervised in the use of this product

### **Other information**

- Do not use if packet is torn, cut or opened
- Store at room temperature, 15° to 30°C (59° to 86°F)
- Avoid contact with eyes

**Inactive Ingredients**

PEG 400, PEG 3350, peppermint oil, sodium saccharin, sorbic acid

**Principal Display Panel – 0.5 gram Packet****Dental Relief**

Active ingredients: Benzocaine (20%), Compound benzoin tincture

USES: Temporarily relieves pain due to canker sores, minor irritation of the mouth and gums caused by dentures or orthodontic appliances, or minor mouth and gum injuries.

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NET WT 0.5g

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**For complete warnings and inactive ingredients, see drug facts card.**

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Mfd. for  **first aid direct**® Mason, OH 45040 800-327-2704

## Principal Display Panel – Pocket Card

### Dental Relief

PROFESSIONAL STRENGTH  
RELIEVES DENTAL PAIN

COMPARE TO ORAJEL

SEE DRUG FACTS CARD  
FOR COMPLETE WARNINGS

560718

12/13

Xpect  
First aid

# DENTAL RELIEF

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**Xpect™**  
*First aid* 

560718  
12/13

## DENTAL RELIEF

benzocaine liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68421-8100
<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) (benzo caine - UNII:U3RSY48JW5)	benzocaine	200 mg in 1 g

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>polyethylene glycol 400</b> (UNII: B697894SGQ)	
<b>polyethylene glycol 3350</b> (UNII: G2M7P15E5P)	
<b>peppermint oil</b> (UNII: AV092KU4JH)	
<b>saccharin sodium</b> (UNII: SB8ZUX40TY)	
<b>sorbic acid</b> (UNII: X045WJ989B)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68421-8100-3	10 in 1 BAG	05/06/2016	
1	NDC:68421-8100-2	0.5 g in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:68421-8100-4	500 in 1 BOX	05/06/2016	
2	NDC:68421-8100-2	0.5 g in 1 PACKET; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	05/06/2016	

**Labeler** - Cintas First Aid & Safety (056481716)**Registrant** - Safetec of America, Inc. (874965262)**Establishment**

Name	Address	ID/FEI	Business Operations
Safetec Of America, Inc.		874965262	MANUFACTURE(68421-8100)

Revised: 2/2014

Cintas First Aid &amp; Safety