PAIN RELIEF- benzocaine liquid
Safetec of America, Inc.

61010-8100-1,-2, Pain Relief

Active Ingredients

Benzocaine 20% (w/w)

Purpose

Oral pain reliever

Uses

temporarily relieves pain caused by

- toothache
- dental work
- minor irritation or injury of the mouth and gums
- canker sores
- gum sores
- cheek bites
- denture irritation

Warnings

For oral use only. Avoid contact with eyes.

Methemoglobinemia warning: Use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. This can occur even if you have used this product before. Stop use and seek immediate attention if you or a child in your care develops:

- pale, gray, or blue colored skin (cyanosis)
- headache
- rapid heart rate
- shortness of breath
- dizziness or lightheadedness
- fatigue or lack of energy

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. If a skin reaction occurs, stop use and seek medical help right away.

Do not use

- for teething
- in children under 2 years of age

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. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- adults and children 2 years of age 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.
- children under 2 years of age: do not use

Other Information

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

Inactive ingredients

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

Questions or Comments?

1-800-456-7077

Principal Display Panel - Safetec Oral Pain Relief Carton Label

NDC 61010-800-1

Safetec

First Aid

Oral Pain Relief

Fast mouth sore relief for:

Canker Sores

Gum Pain

Toothache

Dental Work

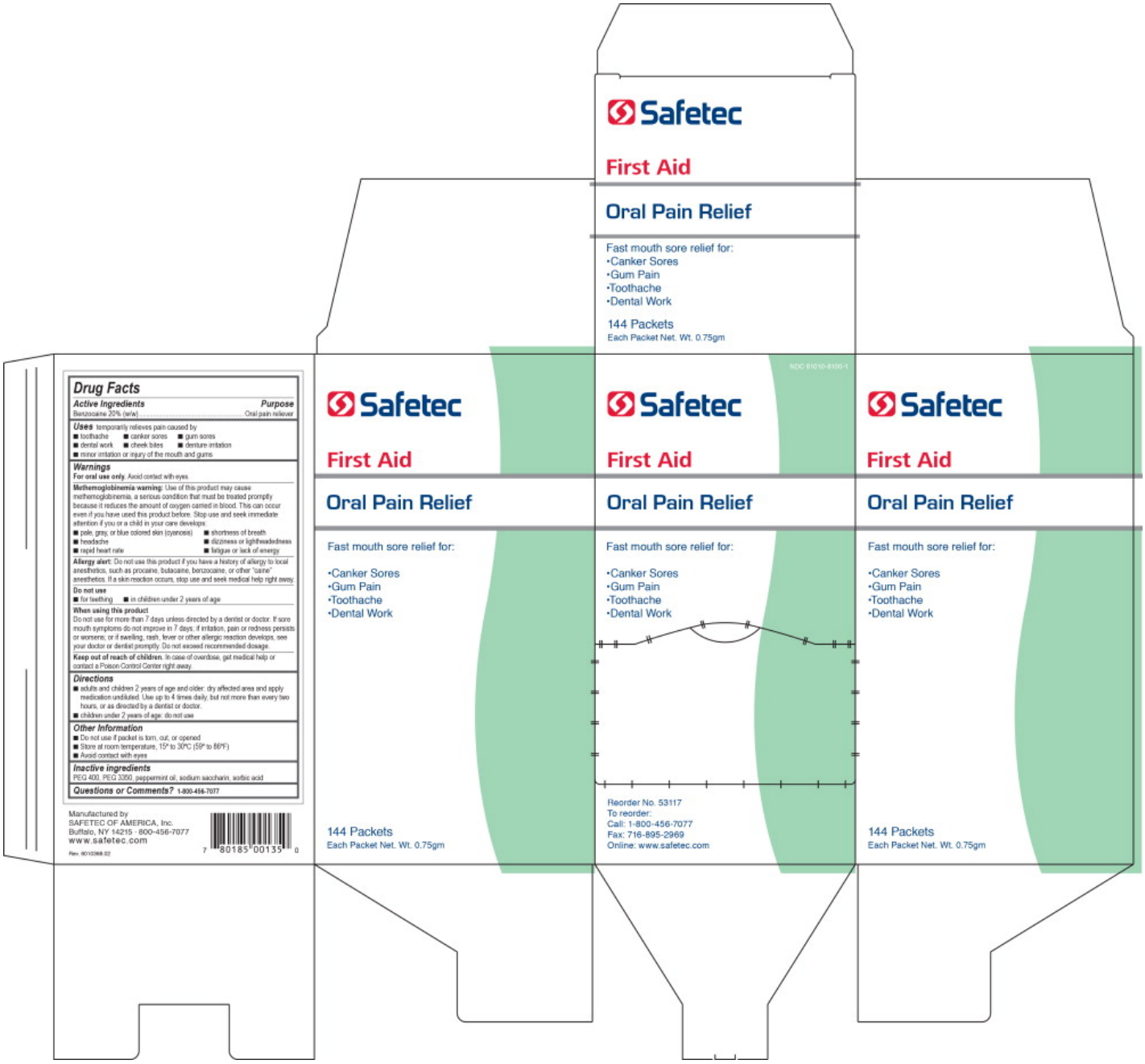
Reorder No. 53117

To reorder:

Call: 1-800-456-7077

Fax: 716-895-2969

Online: www.safetec.com



Principal Display Panel - Safetec Oral Pain Relief Packet Label

Safetec

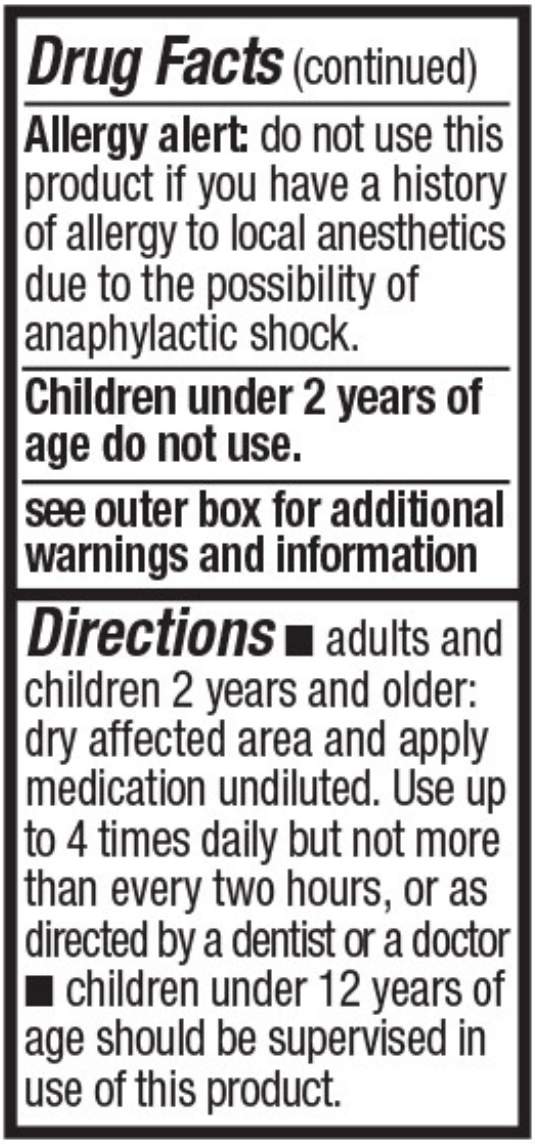
Oral Pain Relief

0.75 g (1/38 oz.)

Safetec of America, Inc.

Buffalo, NY 14215

800-456-7077



PAIN RELIEF
benzocaine liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61010-8100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	200 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBIC ACID (UNII: X045WJ989B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61010-8100-2	0.5 g in 1 PACKET; Type 0: Not a Combination Product	02/01/2019	
2	NDC:61010-8100-1	144 in 1 BOX	02/01/2019	
2		0.75 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 Drug	M017	05/01/2010	

Labeler - Safetec of America, Inc. (874965262)

Establishment

Name	Address	ID/FEI	Business Operations
Safetec Of America, Inc.		874965262	manufacture(61010-8100)

Revised: 2/2024 Safetec of America, Inc.