

SHEFFIELD PAIN RELIEF- benzocaine gel
Sheffield Pharmaceuticals LLC

Drug Facts

Active Ingredient

Benzocaine 20%

Purpose

Oral Pain Reliever

Uses

- temporary relief of occasional minor irritation, pain and sore mouth

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

- more than directed
- for 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 worsens

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

Directions

- do not use tube if it is cut prior to opening
- cut open tip of tube on score mark
- use your fingertip or cotton applicator to apply a small pea-size amount of Oral Pain Relief Gel
- apply to affected area up to four times daily or as directed by a dentist or physician
- Adults and children 2 years of age and older: Apply to affected area
- Children under 12 years of age should be supervised in the use of this product
- Children under 2 years of age: Consult a doctor

Other information

- store at a controlled room temperature 59°-86°F (15°-30°C)

Inactive ingredients

Flavor, PEG 540, PEG 6, PEG 75, PEG 8, Sodium Saccharin, Sorbic Acid

Principal Display Panel - 0.33oz Carton Label

Sheffield Pharmaceuticals

NDC 11527-062-47

Oral Pain Relief

Maximum Strength GEL

Fast Toothache Pain Reliever

20% Benzocaine Topical Gel

NET WT. 0.33 OZ (9.35g)

Made in the USA



See carton for full labeling *Questions?* 1-800-222-1087 2501743
 Distributed by: Sheffield Pharmaceuticals, 170 Broad Street New London, CT 06320
 www.sheffieldpharma.com **Made in USA** OF U.S. & Imported Ingredients and Components



NDC 11527-062-47

**Maximum Strength
 Fast Toothache Pain Reliever**

Oral Pain Relief

GEL



20% Benzocaine Topical Gel NET WT. 0.33 OZ (9.35g)

Active ingredient Benzocaine 20% **Purpose** Oral Pain Reliever
Uses ▪ temporary relief of occasional minor irritation, pain and sore mouth.

Warnings **METHEMOGLOBINEMIA WARNING:** Use of this product may cause methemoglobinemia, a rare but serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. Stop use and seek immediate medical 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. **Do not use** ▪ more than directed ▪ for 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 worsens.

Keep out of reach of children. ▪ In case of overdose, get medical help or contact a Poison Control Center right away. **Directions** ▪ do not use tube if it is cut prior to opening ▪ cut open tip of tube on score mark ▪ use your fingertip or cotton applicator to apply a small pea-size amount of Oral Pain Relief Gel ▪ apply to affected area up to four times daily or as directed by a dentist or physician. ▪ Adults and children 2 years of age and older: Apply to affected area. ▪ Children under 12 years of age should be supervised in the use of this product. ▪ Children under 2 years of age: Consult a doctor.



SHEFFIELD PAIN RELIEF

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11527-062
Route of Administration	ORAL		

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 300 (UNII: 5655G9Y8AQ)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
Saccharin Sodium (UNII: SB8ZUX40TY)	
Sorbic Acid (UNII: X045WJ989B)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	SPEARMINT (SPEARMINT)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11527-062-47	1 in 1 CARTON	01/30/2006	
1		9.35 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:11527-062-55	1 in 1 CARTON	01/30/2006	02/01/2006
2		9.35 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	01/30/2006	

Labeler - Sheffield Pharmaceuticals LLC (151177797)

Establishment

Name	Address	ID/FEI	Business Operations
Sheffield Pharmaceuticals LLC		151177797	MANUFACTURE(11527-062)

Revised: 2/2025

Sheffield Pharmaceuticals LLC