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

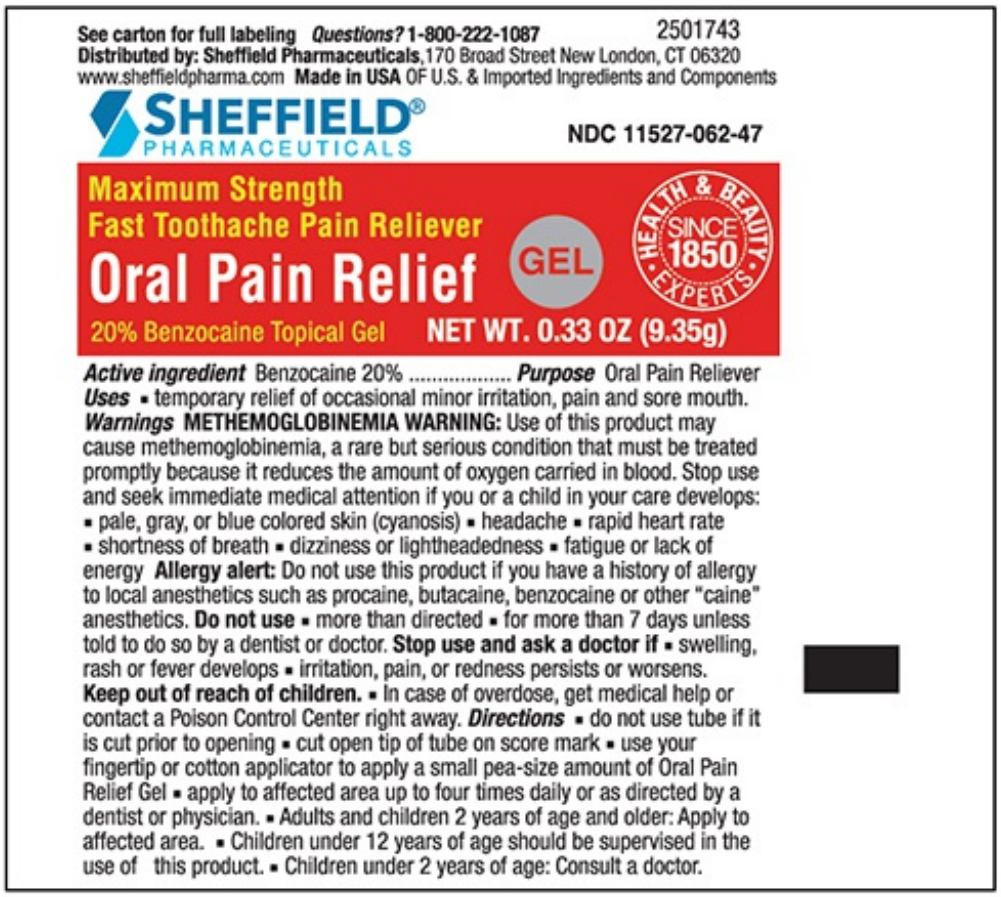
Maxium Strength GEL

Fast Toothache Pain Reliever

20% Benzocaine Topical Gel

NET WT. 0.33 OZ (9.35g)

Made in the USA



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