SHEFFIELD PAIN RELIEF- benzocaine gel
Faria LLC dba Sheffield Pharmaceuticals

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.

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

NDC 11527-062-47

Oral Pain Relief

MAXIMUM STRENGTH GEL

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

Dr. Sheffield's

SHEAF-FIELD

Made in the USA

Principal Display Panel – 0.33oz Tube Label

NDC 11527-062-47

Oral Pain Relief

MAXIMUM STRENGTH GEL

Benzocaine 20%

Dr. Sheffield's

SHEAF-FIELD

Made in the USA

The Adult Medicine for Toothache

Fast Toothache Pain Reliever

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*** **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. 2501741

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SHEAF-FIELD™

Oral Pain Relief

MAXIMUM STRENGTH GEL ***Benzocaine 20%***

Made in the USA **The Adult Medicine for Toothache**

Fast Toothache Pain Reliever **NET WT. 0.33 OZ (9.35g)**

SHEFFIELD PHARMACEUTICALS
www.sheffield-pharmaceuticals.com

New London, CT 06320 USA
Questions? 1-800-222-1087

SHEFFIELD PAIN RELIEF

benzocaine gel

Product Information

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

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:11527-062-55	1 in 1 CARTON		
1		9.35 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	01/30/2006	

Labeler - Faria LLC dba Sheffield Pharmaceuticals (151177797)

Establishment

Name	Address	ID/FEI	Business Operations

Faria LLC dba Sheffield Pharmaceuticals		151177797	MANUFACTURE(11527-062)