

BENZOCAINE- benzocaine gel
Bellus Medical, LLC

20% Benzocaine Gel

Benzocaine 20%

EthylAlcohol, PEG-8, Purified Water, Carbomer, Phenoxyethanol, Caprylyl Glycol, Sorbic Acid

USES: For the temporary relief of discomfort and pain associated with

- minor burns and skin irritations
- minor cuts and scrapes
- itching

DIRECTIONS: Adults and children 12 years of age and older: Apply to affected area not more than 3-4 times daily.

For external use only. Avoid contact with the eyes.

Stop use and ask a doctor if:

- Skin becomes irritated
- Condition worsens or symptoms last more than 7 days
- Symptoms clear up and reoccur within a few days

DO NOT USE: in large quantities, particularly over raw surfaces or blistered areas.

Topical Anesthetic

USES: For the temporary relief of discomfort and pain associated with

- minor burns and skin irritations
- minor cuts and scrapes
- itching

DIRECTIONS: Adults and children 12 years of age and older: Apply to affected area not more than 3-4 times daily.

Keep out of reach of children.

<p>DRUG FACTS Active Ingredients Benzocaine 20% Purpose Topical Anesthetic</p> <p>USES: For the temporary relief of discomfort and pain associated with - minor burns and skin irritations - minor cuts and scrapes - itching.</p> <p>DIRECTIONS: Adults and children 12 years of age and older: Apply to affected area not more than 4 times daily.</p> <p>WARNINGS: For external use only. Avoid contact with the eyes.</p> <p>DO NOT USE: In large quantities, particularly over raw surfaces or blistered areas.</p> <p>Stop use and ask a doctor if - skin becomes irritated - condition worsens or symptoms last more than 7 days - symptoms clear up and reoccur within a few days.</p> <p>INACTIVE INGREDIENTS: Ethyl Alcohol, PEG-8, Purified Water, Carbonic Dioxide, Phenylethanol, Caprylyl Glycol, Sorbic Acid.</p> <p>Other Information: Questions or Comments? Call 888.372.2882 or visit bellusmedical.com. Distributed exclusively by Bellus Medical, LLC, Addison, Texas 75001 USA.</p> <p>PNUMBB REV. B</p>	<p>DRUG FACTS Active Ingredients Benzocaine 20% Purpose Topical Anesthetic</p> <p>USES: For the temporary relief of discomfort and pain associated with - minor burns and skin irritations - minor cuts and scrapes - itching.</p> <p>DIRECTIONS: Adults and children 12 years of age and older: Apply to affected area not more than 4 times daily.</p> <p>WARNINGS: For external use only. Avoid contact with the eyes.</p> <p>DO NOT USE: In large quantities, particularly over raw surfaces or blistered areas.</p> <p>Stop use and ask a doctor if - skin becomes irritated - condition worsens or symptoms last more than 7 days - symptoms clear up and reoccur within a few days.</p> <p>INACTIVE INGREDIENTS: Ethyl Alcohol, PEG-8, Purified Water, Carbonic Dioxide, Phenylethanol, Caprylyl Glycol, Sorbic Acid.</p> <p>Other Information: Questions or Comments? Call 888.372.2882 or visit bellusmedical.com. Distributed exclusively by Bellus Medical, LLC, Addison, Texas 75001 USA.</p> <p>PNUMBB REV. B</p>	<p>BELLUS MEDICAL</p> <p>B</p> <p>20% BENZOCAINE</p> <p>.14FL OZ/4ML</p>	<p>BELLUS MEDICAL</p> <p>B</p> <p>20% BENZOCAINE</p> <p>.14FL OZ/4ML</p>
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BENZOCAINE

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71888-101
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 mL

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 400 (UNII: B6978945GQ)	
SORBIC ACID (UNII: X045WJ989B)	
PHENOXYETHANOL (UNII: H1E492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ALCOHOL (UNII: 3K9958V90M)	
WATER (UNII: 059QF0KO0R)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71888-101-02	12 in 1 BOX	06/01/2017	
1	NDC:71888-101-01	4 mL 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	06/01/2017	

Labeler - Bellus Medical, LLC (005677967)

Registrant - Bellus Medical, LLC (005677967)

Revised: 5/2023

Bellus Medical, LLC