

**AMERICAINE- benzocaine aerosol, spray**  
**Insight Pharmaceuticals LLC**

*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.*

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**Americaine Topical Spray**

**Americaine®**  
**Benzocaine**  
**Topical Anesthetic Spray**

***Drug Facts***

**Active ingredient**

Benzocaine 20%

**Purpose**

Topical Anesthetic

**Uses**

temporarily relieves pain and itching associated with:

- minor cuts
- scrapes
- minor burns
- insect bites

**Warnings**

**For external use only**

**Flammability Warning**

Contents under pressure. Do not puncture or incinerate. Flammable mixture; do not use near fire or flame, or expose to heat or temperatures above 49°C (120°F). Use only as directed. Intentional misuse by deliberately concentrating and inhaling contents can be harmful or fatal.

**When using this product**

avoid contact with the eyes

**Stop use and ask a doctor if**

- condition worsens, or symptoms persists for more than 7 days
- symptoms do not get better, or if redness, irritation, swelling, pain or other symptoms occur or increase

**Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

**Directions**

- **shake can well**, hold 6" to 12" from affected area; spray liberally.
- **adults and children 2 years of age and older:** apply to affected area not more than 3 to 4 times daily
- **children under 2 years of age:** consult a physician

**Inactive ingredients**

Polyethylene glycol 300

**Propellant:** Isobutane, normal butane, propane

**Store at room temperature 15°– 25°C (59°– 77°F).**

**Questions?**

1-800-344-7239

**PRINCIPAL DISPLAY PANEL - 2 OZ Spray Label**

**Americaine®**

Benzocaine

Topical Anesthetic Spray

**NET WT. 2 OZ (57 G)**

Hospital Formula



Americaine<sup>®</sup>

Benzocaine  
Topical Anesthetic Spray

Shake Well Before Use

Maximum Strength  
20% Benzocaine

Stops the pain and itch fast.  
For minor cuts, scrapes,  
burns and sunburns.

NET WT. 2 OZ (57 G)

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Benzocaine 20%.....	Topical anesthetic

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- minor cuts ■ scrapes ■ minor burns ■ insect bites

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Questions? 1-800-344-7239  
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DOT 2Q  
Made in INDIA MH/DRUGS/AD/009 AM003501



## AMERICAINE

benzocaine aerosol, spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63736-378
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	11.4 g in 57 g

**Inactive Ingredients**

Ingredient Name	Strength
ISOBUTANE (UNII: BXR49 TP6 11)	
POLYETHYLENE GLYCOL 300 (UNII: 5655G9 Y8 AQ)	
PROPANE (UNII: T75W99 11L6)	

**Product Characteristics**

Color	WHITE (clear)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63736-378-02	57 g in 1 CAN; Type 0: Not a Combination Product	07/14/2009	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	07/14/2009	

**Labeler** - Insight Pharmaceuticals LLC (055665422)

Revised: 1/2020

Insight Pharmaceuticals LLC