AMERICAINE- benzocaine ointment
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.

Americaine Hemorrhoidal Ointment

Drug Facts

Active ingredient

Benzocaine 20%

Purpose

Hemorrhoidal Ointment

Uses

temporarily relieves these symptoms associated with hemorrhoids

- inflammation
- itching
- local pain
- soreness

Warnings

For external use only

When using this product

- certain persons can develop allergic reactions to ingredients in this product
- do not put this product into the rectum by using fingers or any mechanical device or applicator
- do not exceed dosage unless directed by a doctor

Stop use and ask a doctor if

- condition worsens or does not improve in 7 days
- bleeding occurs
- 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

Adults

- when practical, cleanse affected area with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or soft cloth before application of this product.
- apply externally to the affected area up to 6 times daily

Children under 12 years: ask a doctor

Other information

- if ointment contacts clothing or other fabrics, wash in warm water only; do not use bleach.
- store at room temperature 15°– 25°C (59°– 77°F)
- tube is sealed for your protection. Do not use if foil seal is broken or missing.

Inactive ingredients

benzethonium chloride, polyethylene glycol 300, polyethylene glycol 3350.

QUESTIONS?

Call 1-800-344-7239 or visit our website at **www.insightpharma.com**

Distributed by: Insight Pharmaceuticals LLC

Tarrytown, NY 10591

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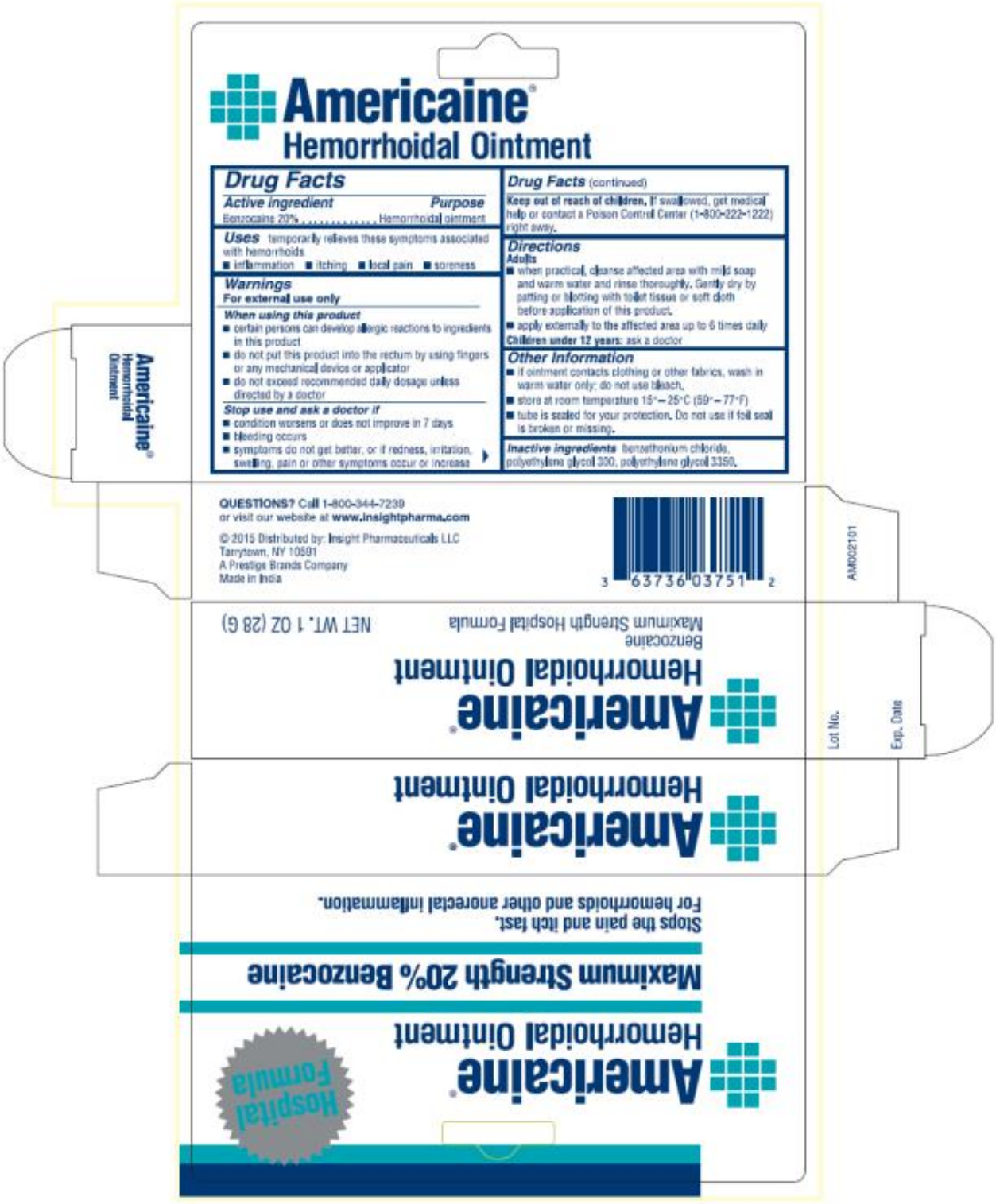
PRINCIPAL DISPLAY PANEL:

Americaine®
Benzocaine
Hemorrhoidal Ointment

NET WT. 1 OZ (28 G)



AMERICAINE

benzocaine ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63736-375
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	5.6 g in 28 g

Inactive Ingredients	
Ingredient Name	**Strength**
BENZETHONIUM CHLORIDE (UNII: PH41D05744)	
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	

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:63736-375-01	1 in 1 BOX	07/10/2009	
1		28 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 FINAL	part346	07/10/2009	

Labeler - Insight Pharmaceuticals LLC (055665422)

Revised: 1/2020 Insight Pharmaceuticals LLC