HURRICAINE- topical anesthetic spray
Beutlich Pharmaceuticals LLC

HurriCaine One

Drug Facts

Active Ingredient

Benzocaine 20%

Purpose

Oral Anesthetic

Uses

Uses for the temporary relief of occasional minor irritation and pain associated with sore mouth and throat

Warnings

Methemoglobinemia warning: Use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. This can occur even if you have used this product before. Stop use and seek immediate medical attention if you or a child in your care develops:
• pale, gray, or blue colored skin (cyanosis)
• headache
• rapid heart rate
• shortness of breath
• dizziness or lightheadedness
• fatigue or lack of energy

Allergy alert: Do not use if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics.

Sore throat warning: if sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, or irritation, pain, or redness persists or worsens, see your dentist or doctor promptly.

Do not use

Do not Use

- if foil pouch has been previously opened

- for teething
- in children under 2 years of age

When using this product
- avoid contact with eyes

Keep out of reach of children.

If more than used for pain is accidently swallowed, get medical help or contact a Poison Control Center Immediately

Directions
- do not exceed recommended dosage

adults and children 2 years of age and older: use up to 4 times daily or as directed by a dentist or doctor

children under 12 years of age: should be supervised in the use of the product

children under 2 years of age: do not use

Other information
- store at 15-30 °C (59-86 °F)

Inactive ingredients

flavor, polyethylene goycol, sodium saccharin

Questions or comments?

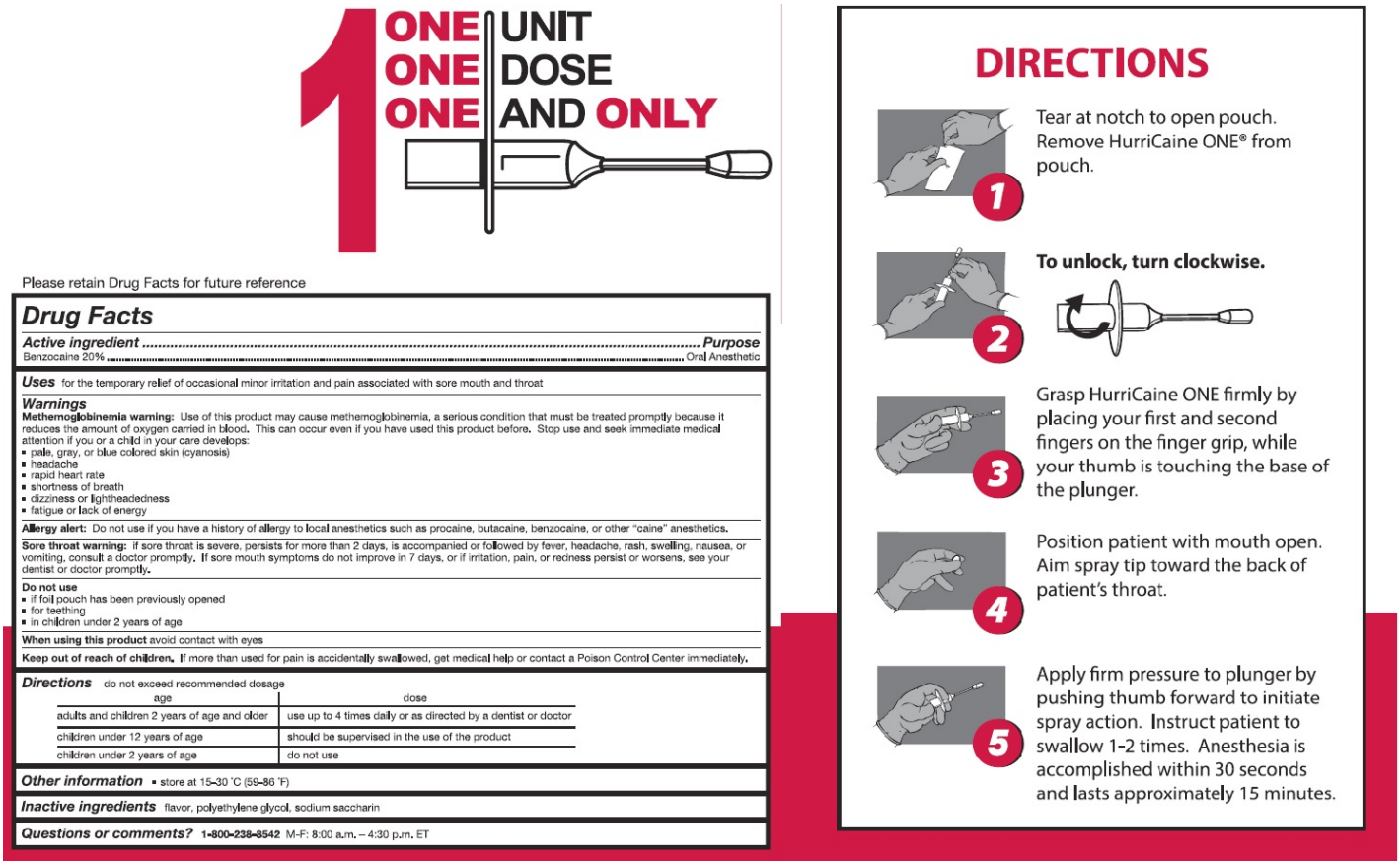
1-800-238-4582

M-F: 8:00 a.m. - 4:30 p.m. ET

Principal Display Panel

HurriCaine One 2ct carton

Principal Display Panel



HurriCaine One 25ct carton

HURRICAINE

topical anesthetic spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0283-0610
Route of Administration	PERIODONTAL, DENTAL		

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 400 (UNII: B697894SGQ)	349 mg in 1 g
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	12 mg in 1 g
CHERRY (UNII: BUC5I9595W)	439 mg in 1 g

Product Characteristics			
Color		**Score**	
Shape		**Size**	

Flavor	CHERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0283-0610-11	2 in 1 BOX	04/01/2016	
1	NDC:0283-0610-43	0.492 g in 1 APPLICATOR; Type 0: Not a Combination Product		
2	NDC:0283-0610-26	25 in 1 BOX	04/01/2016	
2	NDC:0283-0610-43	0.492 g in 1 APPLICATOR; 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	06/15/2010	

Labeler - Beutlich Pharmaceuticals LLC (005209325)

Registrant - Beutlich Pharmaceuticals LLC (005209325)

Establishment

Name	Address	ID/FEI	Business Operations
Beutlich Pharmaceuticals, LLC		005209325	label(0283-0610) , pack(0283-0610)

Revised: 2/2024 Beutlich Pharmaceuticals LLC