

**NEUTRACAINE- benzocaine hydrochloride powder, for solution**  
**Invado 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.*

-----

**NeutraCaine**

**NeutraCaine (Calcium Phosphate Rinse with Benzocaine)**

**Drug Facts**

**Active Ingredients (in each packet)**

Benzocaine hydrochloride 90 mg (3mg/ml)

**Purpose**

Analgesic

**Uses**

For temporary relief of inflammation and pain in the oral cavity:

\* mouth \* tongue \*cheeks

**Warnings**

**This product contains benzocaine.** The use of benzocaine applied to the mouth or gums has been associated with methemoglobinemia (a condition where the amount of oxygen in the blood stream is reduced).

**Stop using**

**immediately if you experience any of the following symptoms and seek medical attention:**

- Pale, gray or blue colored skin, lips, or nail beds
- Headache or lightheadedness

**Ask a doctor if:**

- Sore mouth symptoms do not improve in 7 days
- Irritation, pain or swelling persists or worsens

**When using this product:**

- NeutraCaine® must be mixed with water before use
- NeutraCaine® rinse should not be swallowed
- NeutraCaine® rinse should be spit out after use

**If pregnant or breast feeding,**

ask a health professional before use

**Keep out of reach of children**

- If swallowed, immediately call Poison Control Center or doctor.

## Directions

Dissolve one packet of NeutraCaine® in a clean glass of 30 mL (1 ounce) of tap water. Distilled, bottled or purified water can also be used. Use immediately after the solution appears clear or nearly clear in the glass, or in about 15 seconds. Stir if necessary

- (1) Swish 1/2 the solution in the mouth for 1 min and spit out.
- (2) Repeat with the remaining 1/2 of the solution and spit out

Adults and children 12 years and over	Use NeutraCaine up to 4 times per day, as needed; Do not exceed recommended dosage
Children under 12 years of age	Use NeutraCaine up to 4 times per day, as needed; Should be supervised by an adult; Do not exceed recommended dosage
Children under 2 years	Ask a doctor or dentist

## DO NOT USE

**FOR MORE THAN 7 DAYS UNLESS DIRECTED BY PHYSICIAN**

## Other information

- Store at room temperature ■ Avoid excessive heat or moisture
- Do not use if foil packet is opened or shows signs of leakage or damage

## Inactive ingredients

Calcium Chloride, Sodium Phosphate, Sodium Chloride, Sodium Bicarbonate, Cherry Flavoring

Manufactured for Invado Pharmaceuticals, LLC

Pomono, NY 10970

Made in Canada

[www.NeutraCaine.com](http://www.NeutraCaine.com)

Patents Pending

UPC Code 793573756282

## Package/Label Principal Display Panel

NDC 49939-201-01

NeutraCaine

(Calcium Phosphate Rinse with Benzocaine)

For relief of oral mucocitis pain

Mix with water before use

30 Packets Dissolving Powder

491 mg per packet | Net wt.14.73g



## NEUTRACAINE

benzocaine hydrochloride powder, for solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49939-201
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BENZO CAINE HYDRO CHLORIDE</b> (UNII: OG625Z9LEO) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE HYDROCHLORIDE	90 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>CALCIUM CHLORIDE</b> (UNII: M4I0D6VV5M)	
<b>SODIUM PHOSPHATE</b> (UNII: SE337SVY37)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)	

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49939-201-01	30 in 1 CARTON		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part356	03/07/2014	

**Labeler** - Invado Pharmaceuticals, LLC (831722199)

Revised: 4/2014

Invado Pharmaceuticals, LLC