

SALIVACAINE- benzocaine powder, for solution
Forward Science Technologies 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.

SalivaCAINE

Active ingredient

Benzocaine 5% (w/v)

Purpose: oral pain reliever

Uses

For temporary relief of occasional minor oral irritation, oral pain, and sore mouth.

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 • dizziness or lightheadedness
- rapid heart rate • shortness of breath
- fatigue or lack of energy

Allergy alert

Do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine, or any other ‘caine’ anesthetics. If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning

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

Do Not Use

Do not use

- for teething
- in children under 2 years of age

Keep out of reach of children

Keep out of reach of children

Directions

Adults and children 2 years of age and older:

Mix packet with 0.1oz water and apply the rinse to the affected area. Gargle, swish around in the mouth, or allow to remain in place 1 minute then Spit Out.

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

Inactive ingredients

Calcium Chloride, Dibasic Sodium Phosphate, Monobasic Sodium Phosphate, Silicon Dioxide, Sodium Chloride

Questions

Call 1-855-696-7254 (M - F 8:30 - 5:30 CST)

You may also report side effects to this phone number.

oral pain reliever

NDC 70275-0406-03

SalivaCAINE

Oral Pain Reliever

(Benzocaine 5%)

30 Packets Dissolving Powder

Mix with water before use

Benzocaine 150mg/0.1oz

418mg per packet - 12.54g total



SALIVACAINE

benzocaine powder, for solution

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70275-406 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--------------------------------------------------------------|-------------------|-------------------|
| BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5) | BENZOCAINE | 150 mg in 3000 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------------------------|----------|
| SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |

CALCIUM CHLORATE DIHYDRATE (UNII: BBB2RG413E)

SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7I04HPUU)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|-------------------------------------------------------|----------------------|--------------------|
| 1 | NDC:70275-406-03 | 30 in 1 CARTON | 02/24/2017 | |
| 1 | | 150 mg 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 not final | part356 | 02/24/2017 | |

Labeler - Forward Science Technologies LLC (079212068)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------------------|---------|-----------|------------------------|
| Forward Science Technologies LLC | | 079212068 | manufacture(70275-406) |

Revised: 1/2020

Forward Science Technologies LLC