ONRAL ORAL PAIN RELIEVER MOUTHWASH- benzocaine liquid
Syka Pharma Inc.

Onral Oral Pain Reliever Mouthwash

Drug Facts

Active ingredient

Benzocaine 5%

Purpose

Oral Pain Reliever

Uses

For the temporary relief of minor irritation, pain, sore mouth, and sore throat.

Warnings

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 if irritation, pain, or redness persists or worsens, see your dentists or doctor promptly.

- Do not exceed recommended dosage.

Do not use

- this product if you have a history of allergy to local anesthetics such as procaine, butacaine, or other "caine" anesthetics.

Methemoglobinemia warning:

Use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduce 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)
- rapid heart rate
- dizziness or lightheadedness
- headache
- shortness of breath
- atigue or lack of energy

Keep out of reach of children

Directions

- Shake well upside down.
- Gargle, swish around in the mouth, or allow to remain in place for at least 1 minute and then spit out.
- Children under 12 years of age should be supervised in the use of the product.
- Apply to the affected area.
- Use up to 4 times daily or as directed by a dentist or doctor.
- Do not use for teething.
- Children under 2 years of age: Do not use.

Other information

store at 68-77 ° F (20-25 ° C)

Inactive ingredients:

Purified water, Vegetable glycerin, PEG 400, Sorbitol, Polysorbate 80, Natural orange flavor, Potassium sorbate, Xanthan gum, Citric acid, Beta-carotene.

Package Labeling:

ONRAL ORAL PAIN RELIEVER MOUTHWASH

benzocaine liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:85454-0421
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SORBITOL (UNII: 506T60A25R)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
BETA CAROTENE (UNII: 01YAE03M7J)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85454-0421-1	1 in 1 CARTON	07/01/2025	
1		230 mL in 1 BOTTLE, PLASTIC; 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	07/01/2025	

Labeler - Syka Pharma Inc. (243334603)

Registrant - Delta Pharma Inc (200161730)

Revised: 6/2025 Syka Pharma Inc.