# ANESTHETIC LOZENGES HONEY LIME FLAVORS- benzocaine, menthol lozenge PRASON FOODS

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.

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### **Active Ingredient**

Benzocaine 15 mg

Menthol 2.6 mg

### **Purpose**

Oral anesthetic

#### Uses

Temporarily relieves occasional minor irritation, pain, sore throat and sore mouth.

### Warning

### Methemoglobinemia warning

Use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduced 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, grey, or blue colored skin (Cyanosis)
- Headache
- Rapid heart ache
- Shortness of breath
- Dizziness or light headedness
- Fatigue or lack of energy

### 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 if irritation, pain or redness persist or worsens, see your dentist or doctor promptly.

#### Do not use

- For teething
- In children under 5 years of age

### Stop use and ask doctor if

• Sore mouth symptoms do not improve in 7 days.

If pregnant or breast-feeding, ask a health professional before use.

**Keep out of reach of children.** In case of overdose, get medical help or contact Poison Control Center right away.

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

#### **Directions**

### Adults and children 5 years and older:

Allow 1 lozenge to dissolve slowly in mouth. May be repeated every two hours as necessary or as directed by a doctor.

Children under 5 years: Do not use.

#### Other Information

- Store at room temperature
- Protect from moisture.

TEMPER EVIDENT PACKAGING. DO NOT USE IF OUTER BOX OR BLISTER IS OPENED OR DAMAGED.

### Inactive ingredients

Acesulfame k, Citric acid, Honey lime flavor, Liquid glucose, Sucrose, Tartaric acid, Tartrazine and Water

### **Product label**

### Drug Facts

#### Active Ingredients (in each lozenge) Purpose

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Menthol 2.6 mg .....Oral anesthetic

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### Drug Facts(continued)

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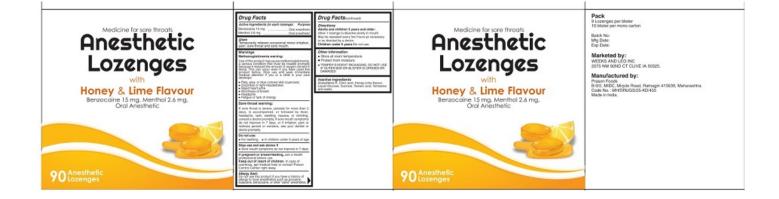
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benzocaine, menthol lozenge

#### **Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83348-002
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	15 mg	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2.6 mg	

Inactive Ingredients			
Ingredient Name	Strength		
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)			
SUCROSE (UNII: C151H8M554)			
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)			
TARTARIC ACID (UNII: W4888I119H)			
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)			
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)			
WATER (UNII: 059QF0KO0R)			

Product Characteristics				
Color	yellow	Score	no score	
Shape	ROUND	Size	18mm	
Flavor	HONEY (Honey and Lime)	Imprint Code	NO	
Contains				

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83348-002- 01	10 in 1 CARTON	04/15/2023	
1		9 in 1 BLISTER PACK; 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	04/15/2023	

## Labeler - PRASON FOODS (861707089)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations

	PRASON FOODS	861707089	manufacture(83348-002)
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Revised: 5/2023 PRASON FOODS