

## **ANESTHETIC LOZENGES RASPBERRY FLAVOUR- 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, Allura Red AC (FD & Red No.40), Citric acid, Liquid glucose, Raspberry flavor, Sucrose, Tartaric acid and Water

### **Product label**

## Drug Facts

Active Ingredients (in each lozenge)	Purpose
Benzocaine 15 mg	Oral anesthetic
Menthol 2.6 mg	Oral anesthetic

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## Drug Facts<sub>(continued)</sub>

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Acesulfame K, Allura Red AC (FD & Red No. 40), Citric acid, Liquid Glucose, Raspberry flavour, Sucrose, Tartaric acid and Water.

<p>Medicine for sore throats</p> <h1>Anesthetic Lozenges</h1> <p>with Raspberry Flavour</p> <p>Benzocaine 15 mg, Menthol 2.6 mg. Oral Anesthetic</p>  <p>90 Anesthetic Lozenges</p>	<h3>Drug Facts</h3> <p>Active Ingredients (in each lozenge) Purpose Benzocaine 15 mg Oral anesthetic Menthol 2.6 mg Oral anesthetic</p> <p><b>Uses</b> Temporarily relieves occasional minor irritation, pain, sore throat and sore mouth.</p> <p><b>Warnings</b> <b>Methemoglobinemia warning:</b> 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) • Dizziness or light-headedness • Rapid heart ache • Shortness of breath • Headache • Fatigue or lack of energy</p> <p><b>Sore throat warning:</b> 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.</p> <p><b>Do not use:</b> • For teething • In children under 5 years of age</p> <p><b>Stop use and ask doctor if</b> • Sore mouth symptoms do not improve in 7 days. If pregnant or breast-feeding, ask a health professional before use.</p> <p><b>Keep out of reach of children.</b> In case of overdose, get medical help or contact Poison Control Center right away.</p> <p><b>Allergy Alert:</b> Do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine, or other "caine" anesthetics.</p>	<p>Medicine for sore throats</p> <h1>Anesthetic Lozenges</h1> <p>with Raspberry Flavour</p> <p>Benzocaine 15 mg, Menthol 2.6 mg. Oral Anesthetic</p>  <p>90 Anesthetic Lozenges</p>	<p><b>Pack</b> 9 Lozenges per blister 10 blister per mono carton</p> <p>Batch No: Mfg Date: Exp Date:</p> <p><b>Marketed by:</b> WEEKS AND LEO INC 2075 NW 50th CT, CLIVE IA 50325.</p> <p><b>Manufactured by:</b> Parsoon Foods B-02, MIDC, Miraj Road, Ratnagiri 415639, Maharashtra. Code No. :MAHVRUGS25-KD455 Made in India.</p>
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# ANESTHETIC LOZENGES RASPBERRY FLAVOUR

benzocaine, menthol lozenge

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83348-001
<b>Route of Administration</b>	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
<b>DEXTROSE, UNSPECIFIED FORM</b> (UNII: IY9XDZ35W2)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)	
<b>TARTARIC ACID</b> (UNII: W4888I119H)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>WATER</b> (UNII: 059QF0KO0R)	

Product Characteristics

<b>Color</b>	red	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	18mm
<b>Flavor</b>	RASPBERRY	<b>Imprint Code</b>	NO
<b>Contains</b>			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83348-001-01	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)

Establishment

Name	Address	ID/FEI	Business Operations
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PRASON FOODS		861707089	manufacture(83348-001)
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Revised: 5/2023

PRASON FOODS