

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.

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
Benzocaine 15 mg	Oral anesthetic
Menthol 2.6 mg	Oral anesthetic

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Inactive ingredients

Acesulfame K, Citric acid, Honey-Lime flavour, Liquid Glucose, Sucrose, Tartaric acid, Tartrazine and water.

<p>Medicine for sore throats</p> <h1>Anesthetic Lozenges</h1> <p>with Honey & Lime Flavour</p> <p>Benzocaine 15 mg, Menthol 2.6 mg, Oral Anesthetic</p>  <p>90 Anesthetic Lozenges</p>	<p>Drug Facts</p> <p>Active ingredients (in each lozenge) Purpose Benzocaine 15 mg Oral anesthetic Menthol 2.6 mg Oral anesthetic</p> <p>Uses Temporarily relieves occasional minor irritation, pain, sore throat and sore mouth.</p> <p>Warnings 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: <ul style="list-style-type: none"> ■ 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>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.</p> <p>Do not use: <ul style="list-style-type: none"> ■ For teething ■ In children under 5 years of age </p> <p>Stop use and ask doctor if <ul style="list-style-type: none"> ■ Sore mouth symptoms do not improve in 7 days </p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact Poison Control Center right away.</p> <p>Allergy Alert: 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>Drug Facts^(continued)</p> <p>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.</p> <p>Other Information <ul style="list-style-type: none"> ■ Store at room temperature ■ Protect from moisture. ■ TEMPER EVIDENT PACKAGING. DO NOT USE IF OUTER BOX OR BLISTER IS OPENED OR DAMAGED. </p> <p>Inactive ingredients Acesulfame K, Citric acid, Honey-Lime flavour, Liquid Glucose, Sucrose, Tartaric acid, Tartrazine and water.</p>	<p>Medicine for sore throats</p> <h1>Anesthetic Lozenges</h1> <p>with Honey & Lime Flavour</p> <p>Benzocaine 15 mg, Menthol 2.6 mg, Oral Anesthetic</p>  <p>90 Anesthetic Lozenges</p>	<p>Pack 9 Lozenges per blister 10 blister per mono carton</p> <p>Batch No: Mfg Date: Exp Date:</p> <p>Marketed by: WEEKS AND LEO INC. 2075 NW 92ND CT OLIVE IA 50525.</p> <p>Manufactured by: Pragati Foods B-9/2, MIDC, Mingle Road, Rahmaji, 415639, Maharashtra. Code No.: MH10FUG2525-KD450 Made in India.</p>
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ANESTHETIC LOZENGES HONEY LIME FLAVORS

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	Basis of Strength	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: 23OV73Q5G9)	
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			

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)

Establishment

Name	Address	ID/FEI	Business Operations
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PRASON FOODS		861707089	manufacture(83348-002)
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Revised: 5/2023

PRASON FOODS