

## **RITE AID BABY CARE- benzocaine gel, dentifrice**

### **Rite Aid**

*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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### **Drug Facts**

#### **Active ingredient**

Benzocaine 7.5% ..... Oral pain reliever

#### **Use**

temporarily relieves sore gums due to teething in infants and children 4 months of age and older

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

- Do not use more than directed for more than 7 days unless told to do so by a dentist or doctor.
- When using this product fever and nasal congestion are not symptoms of teething and may indicate the presence of infection. If these symptoms do not go away, advise your dentist or doctor.
- Stop use and ask a doctor if sore mouth symptoms do not get better in 7 days. swelling, rash or fever develops, irritation, pain or redness persists or worsens

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

#### **Directions**

- wash hands
- cut open tip of tube on scoremark
- use your fingertip or cotton applicator to apply a small pea-size amount of gel
- apply to affected area up to four times daily or as directed by a dentist or doctor
- for infants under 4 months of age, ask a dentist or doctor

#### **Other Information**

Do not use if tip is cut prior to opening.

#### **Inactive ingredients**

FD&C Red 40, Flavor, Glycerin, Polyethylene Glycols, Purified Water, Sodium Saccharin, Sorbic Acid, Sorbitol

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\*Compare to the active ingredient in Baby Orajel®

# baby care oral pain relief

benzocaine 7.5%

oral pain reliever for teething

safety sealed tube tip



# baby care oral pain relief

benzocaine 7.5%

oral pain reliever for teething



# baby care oral pain relief

benzocaine 7.5%

oral pain reliever for teething

NET WT 0.5 OZ (14 g)

# baby care oral pain relief

benzocaine 7.5%

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\*This product is not manufactured or distributed by Church & Dwight Co., Inc., owner of the registered trademark Orajel®.

DISTRIBUTED BY:  
Rite Aid  
30 Hunter Lane, Camp Hill PA 17011

MADE IN USA



STRIP IN UPC:  
0-11822-02379  
80% MAGNIFICATION,  
20% TRUNCATION.  
DOTTED RULE  
DOES NOT PRINT.

ITEM 0302379

282131R2  
5820311

**Drug Facts**

**Active ingredient** Benzocaine 7.5%

**Purpose** Oral pain reliever

**Use** temporarily relieves sore gums due to teething in infants and children 4 months of age or older

**Warnings**  
**Allergy alert:** do not use this product if your baby has a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics

**Do not use** • more than directed • for more than 7 days unless told to do so by a dentist or doctor.

**When using this product** • fever and nasal congestion are not symptoms of teething and may indicate the presence of infection. If these symptoms do not go away, advise your dentist or doctor.

**Stop use and ask a dentist or doctor if** • sore mouth symptoms do not get better in 7 days • swelling, rash or fever develops • irritation, pain, or redness persists or worsens.

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

**Directions** • wash hands • cut open tip of tube on score mark • use your fingertip or cotton applicator to apply a small pea-size amount of gel • apply to affected area up to four times daily or as directed by a dentist or doctor • for infants under 4 months of age, ask a dentist or doctor

**Other information** • do not use if tube tip is cut prior to opening

**Inactive ingredients** FD&C Red 40, Flavor, Glycerin, Polyethylene Glycols, Purified Water, Sodium Saccharin, Sorbic Acid, Sorbitol



**\*Compare to the active ingredient in Baby Orajel®**

# baby care oral pain relief

**benzocaine 7.5%**

oral pain reliever for teething

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**DISTRIBUTED BY: RITE AID CORPORATION, 30 HUNTER LANE, CAMP HILL, PA 17011**

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- 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 this product
- children under 2 years of age: consult a dentist or doctor

## RITE AID BABY CARE

benzocaine gel, dentifrice

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-1031
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	7.5 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	

**SORBIC ACID** (UNII: X045WJ989B)

**FD&C RED NO. 40** (UNII: WZB9127XOA)

**WATER** (UNII: 059QF0KO0R)

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY (Characteristic Cherry)	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-1031-9	1 in 1 CARTON		
1	NDC:11822-1031-2	14.0 g in 1 TUBE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	01/20/2011	

**Labeler** - Rite Aid (014578892)

**Registrant** - Lornamead (126440440)

### Establishment

Name	Address	ID/FEI	Business Operations
Lornamead		126440440	manufacture(11822-1031) , pack(11822-1031)

Revised: 1/2013

Rite Aid