WALGREENS BABY TEETHING- benzocaine gel, dentifrice
Walgreens

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.

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

mm1.jpg

Compare to Baby Orajel® Teething Gel active ingredient*

Walgreens

CHERRY FLAVOR

BABY TEETHING GEL

Fast Relief of Teething Pain

Benzocaine 7.5%

NET WT 0.33 OZ (9.4g)

2821326R1
5820326

Oral Pain Reliever for Teething

ORG0712-F

Walgreens

CHERRY FLAVOR

BABY TEETHING GEL

Fast Relief of Teething Pain

Benzocaine 7.5%

NET WT 0.33 OZ (9.4g)

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

DISTRIBUTED BY: WALGREEN CO.
200 WILMOT RD., DEERFIELD, IL 60015

Walgreens 100% SATISFACTION GUARANTEED

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MADE IN U.S.A.

ITEM 175263

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Drug Facts

Active ingredient	Purpose
Benzocaine 7.5%	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

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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

WALGREENS BABY TEETHING

benzocaine gel, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0363-6230
Route of Administration	ORAL	**DEA Schedule**	

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

Color		**Score**	
Shape		**Size**	
Flavor	CHERRY (Characteristic Cherry)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-6230-09	1 in 1 CARTON		
1	NDC:0363-6230-02	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 - Walgreens (008965063)

Registrant - Lornamead (126440440)

Establishment

Name	Address	ID/FEI	Business Operations
Lornamead		126440440	manufacture(0363-6230) , pack(0363-6230)