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

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Walgreens

CHERRY FLAVOR BABY TEETING GEL Fast Relief of Teething Pain Benzocain

NET WT 0.33 OZ (9.4g)

Active ingredient Benzocaine 7,5% Use temporarily relieves sore gums due to teething in infants and children 4 months of age or older Warnings Alliergy 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 one tin of tube on score mark • use your fingertip or cotton applicator to apply a small. 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.

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

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MADE IN U.S.A.

ITEM 175263 1821326R1

• 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

Prod	nct l	Info	rmai	tion

HUMAN OTC DRUG LABEL NDC:0363-6230 Product Type Item Code (Source)

Route of Administration ORAL **DEA Schedule**

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZO CAINE (BENZO CAINE)	BENZOCAINE	7.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 400	
POLYETHYLENE GLYCOL 3350	
SACCHARIN SO DIUM	
SORBITOL	
GLYCERIN	
SORBIC ACID	
FD&C RED NO. 40	
WATER	

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

P	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)

Revised: 1/2013 Walgreens