

CVS FAST ACTING BABY TEETHING - benzocaine gel

CVS Pharmacy

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

Purpose

Benzocaine 10%.....Oral Pain Reliever

Uses

- temporary relieves of sore gums due to teething in infants and children 4 months and older

Keep out of reach of children. If case of overdose or allergic reaction, seek medical attention or contact a Poison Control Center right away.

Uses

- temporary relieves of sore gums due to teething in infants and children 4 months and older

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

Warnings

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

Do not use - more than directed - for more than 7 days, unless directed 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 persist, contact your dentist or doctor.

Stop use and consult a dentist or doctor if:

- sore mouth symptoms do not get better in 7 days
- irritation, pain or redness does not go away - swelling, rash or fever develops

Keep out of the reach of children.In case of overdose or allergic reaction, seek medical attention or contact a Poison Control Center right away.

Directions

- wash hands - cut open tip of tube on score mark
- use your fingertip or cotton swab to apply a small, pea-size amount of product
- apply to the 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 and C red no. 4, flavor, glycerin, propylene glycols, purified water, sodium saccharine, sorbic acid, sorbitol

Drug Facts

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Other information

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Inactive ingredients

FD&C red no. 40, flavor, glycerin, polyethylene glycols, purified water, sodium saccharin, sorbic acid, sorbitol

TAMPER EVIDENT: DO NOT USE IF TUBE TIP IS CUT PRIOR TO USE



#691947



*This product is not manufactured or distributed by DEL Pharmaceuticals, Inc., owner of the registered trademark Baby Orajel® Nighttime Formula

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www.cvs.com
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Di#27598

NET WT 0.18 OZ. (5.3g)

Benzocaine 10%

FOR TEETHING

ORAL PAIN RELIEF

Fast-acting

Compare to the active ingredient in Baby Orajel® Nighttime Formula*



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Benzocaine 10%

FOR TEETHING

ORAL PAIN RELIEF

Fast-acting

CVS pharmacy

Benzocaine 10%

FOR TEETHING

ORAL PAIN RELIEF

Fast-acting

Compare to the active ingredient in Baby Orajel® Nighttime Formula*



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with additional pain reliever

ORAL PAIN RELIEF





CVS FAST ACTING BABY TEETHING

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-829
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	75 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYETHYLENE GLYCOL 1450 (UNII: OJ4Z5Z32L4)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	
WATER (UNII: 059QF0KO0R)	
SORBIC ACID (UNII: X045WJ989B)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY (CHERRY FLAVOR)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-829-53	1 in 1 CARTON		
1		9.4 g in 1 TUBE, WITH APPLICATOR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	07/08/2010	

Labeler - CVS Pharmacy (062312574)

Registrant - Pharma Pac, LLC (140807475)

Establishment

Name	Address	ID/FEI	Business Operations
Pharma Pac, LLC		140807475	manufacture

Revised: 7/2010

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