## 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.

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#### **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

#### Active ingredient

Benzocaine 10% ......

**Purpose** ... Oral Pain Reliever

Uses temporarily relieves sore gums due to teething in infants and children 4 months of age and 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 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 reach of children. In case of overdose or allergic reaction, get medical help or contact a Poison Control Center right away.

#### **Directions**

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   use your fingertip or cotton swab to apply a small, pea-size amount of product
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- 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 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



**4**01644

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



1-800-shop-CVS www.cvs.com

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Die#27598

NET WT 0.18 OZ. (5.3g)

8enzocaine 10%

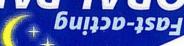
FOR TEETHING



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# AIN BELIEF

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



8enzocaine 10%



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



Mith additional pain reliever



#### 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
BENZO CAINE (UNII: U3RSY48JW5) (BENZO CAINE - UNII: U3RSY48JW5)
BENZO CAINE (The strength of the strength of

Inactive Ingredients				
Ingredient Name	Strength			
GLYCERIN (UNII: PDC6A3C0OX)				
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)				
POLYETHYLENE GLYCOL 1450 (UNII: OJ4Z5Z32L4)				
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)				
SORBITOL (UNII: 506T60A25R)				
FD&C RED NO. 4 (UNII: X3W0 AM1JLX)				
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 CVS Pharmacy