

OLP BABY TEETHING- benzocaine gel
Ohio Lab Pharma

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.

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 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.

Purpose

anaesthetic

Active Ingredient

Benzocaine 7.5%

Other information

store at 15 to 25 C(59-77F)

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 baby teething gel
- apply to affected area up to four times daily or as directed by a dentist or doctor
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for infants under 4 months of age, ask a dentist or doctor

Inactive ingredients

FD&C yellow 5, FD&C Red 40, Flavor, Glycerin, Propylene Glycols, Purified Water, Sorbic Acid, carbomer, methyl paraben, propyl paraben

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 physician

stop using and ask a dentist or physician

- 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 contact a poison control center right away

questions

www.ohiolabpharma.us

NET WEIGHT 0.33 oz (9.4g)

NDC#70648-999-01



OLP BABY TEETHING

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70648-999
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RS Y48JW5) (BENZOCAINE - UNII:U3RS Y48JW5)	BENZOCAINE	7.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SORBIC ACID (UNII: X045WJ989B)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70648-999-01	1 in 1 CARTON	12/06/2017	
1		9.4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	12/06/2017	

Labeler - Ohio Lab Pharma (080215854)**Establishment**

Name	Address	ID/FEI	Business Operations
Ohio Lab Pharma		080215854	manufacture(70648-999)

Revised: 4/2020

Ohio Lab Pharma