NUBY TEETHING GEL- teething gel gel Europharma Concepts limited

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.

Active Ingredient

Eugenol 0.8%





Factory: Longwell Card thickness: 0.032"

Purpose

Oral pain reliever

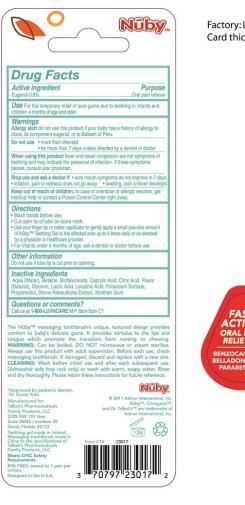




Keep out of reach of children

In case of overdose or allergic reaction, get medical help or contact a Poison Control Center right away.





Factory: Longwell Card thickness: 0.032"

Warnings

Allergy alert do not use this product if your baby has a history of allergy to clove, its component eugenol, or to Balsam of Peru.

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, consult your physician.

Stop use and ask a doctor if

sore mouth symptoms do not improve in 7 days

irritation, pain or redness does not go away





Directions

Wash hands before use.

Cut open tip of tube on score mark.

Use your finger tip or cotton applicator to gently apply a small pea-size amount of Nuby Teething Gel to the affected area up to 4 times daily or as directed by a physician or healthcare provider.

For infants under 4 months of age, ask a dentist or doctor before use.





Inactive Ingredients

Aqua (Water), Betaine, Bioflavonoids, Caprylic Acid, Citric Acid, Flavor (Natural), Glycerin, Lactic Acid, Levulinic Acid, Potassium Sorbate, Propanediol, Stevia Rebaudiana Extract, Xanthan Gum



Use

For the temporary relief of sore gums due to teething in infants and children 4 months of age and older.



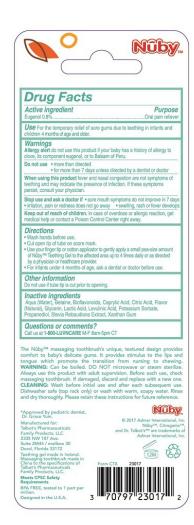


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Principal Display Panel





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NUBY TEETHING GEL

teething gel gel

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:71552-231 Route of Administration TOPICAL

Active Ingredient/Active Moiety				
Basis of Strength	Strength			
EUGENOL	8 mg in 1 g			

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:71552-231-12	12 in 1 CARTON	06/28/2017	
1	3 in 1 CARTON		
1	1 in 1 BLISTER PACK		
1 NDC:71552-231-15	15 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 not final	part356	06/28/2017			

Labeler - Europharma Concepts limited (896333478)

Revised: 6/2017 Europharma Concepts limited