

NUBY TEETHING GEL- teething gel gel
Talbot's Pharmaceuticals Family Products, LLC.

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 1.3% (extracted from Clove Plant)



Purpose

Oral pain reliever

BONUS!!
Gum-eez™ teether

Nuby™
All Natural
Teething Gel with
Gum-eez™ Teether

4m+

INSTANT RELIEF Formula**

Soothes Gums

Safe to Swallow

DENTIST APPROVED

with Citroganix™

BPA FREE

NET WT .53 oz (15 g)

Nuby™

Drug Facts		Drug Facts (continued)
Active ingredient Eugenol 1.3% (extracted from Clove Plant)	Purpose Oral pain reliever	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.
Use For the temporary relief of 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 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 • 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.	Other information Do not use if tube tip is cut prior to opening. Inactive ingredients Aqua (Water), Saline, Biotinoylchitosan, Citric Acid, Flavor (Natural), Glycerin, Glyceryl Caprylate, Glyceryl Undecylate, Lactic Acid, Potassium Sorbate, Propylparaben, Stevia Rebaudiana Extract, Xanthan Gum.
WARNING: Always use this product with adult supervision. Instructions enclosed.		Questions or comments? Call us at 1-800-LUVWCARE M-F 9am-5pm CT

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Nuby™, Citroganix™, Gum-eez™, and Dr. Talbot's™ are trademarks of Admar International, Inc.

Nuby
HOOD

Manufactured for:
Talbot's Pharmaceuticals
Family Products, LLC
2335 NW 107 Ave.
Suite 2M44 / mailbox 30
Doral, Florida 33172

Teething gel made in Ireland to Talbot's Pharmaceuticals Family Products, LLC specifications.
Gum-eez™ made in China.
Meets CPSC Safety Requirements
Designed in the U.S.A.

23015 Form CTX
3 70797 23015 8

*Approved by pediatric dentist, Dr. Grace Yum.
**Begins soothing upon contact with affected area

Keep out of reach of children

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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

swelling, rash or fever develops



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, Citric Acid, Flavor (Natural), Glycerin, Glyceryl Caprylate, Glyceryl Undecelinate, Lactic 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.



Principal Display Panel



NUBY TEETHING GEL

teething gel gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70797-230
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
EUGENOL (UNII: 3T8H1794QW) (EUGENOL - UNII:3T8H1794QW)	EUGENOL	13 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	TUTTI FRUTTI	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70797-230-24	24 in 1 CARTON	12/01/2016	
1		4 in 1 CARTON		
1		1 in 1 BLISTER PACK		
1	NDC:70797-230-15	15 g in 1 TUBE; Type 0: Not a Combination Product		

2133291EX11/16

DR. TALBOT'S

All Natural
Teething Gel



FAST ACTING PAIN RELIEF







Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	12/01/2016	

Labeler - Talbot's Pharmaceuticals Family Products, LLC. (078855555)

Revised: 6/2016

Talbot's Pharmaceuticals Family Products, LLC.