ANADENT CHILDRENS KANKA GEL- eugenol gel Belmora 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.

AnaDent Children's Kanka Gel

Drug Facts

Active Ingredient

Eugenol 1.2%

Purpose

Toothache Relief Agent

Uses:

For the temporary relief of throbbing, persistent toothache.

Warnings:

For external use only.

Allergy alert: Do not use if you are allergic to eugenol (clove oil).

When using this product

- use only in teeth with persistent throbbing pain
- DO NOT SWALLOW to avoid irritation avoid contact with eyes

Do not use

• for more than 7 days • more than the recommended dose

Stop use and ask a dentist or doctor if

• irritation persists • inflammation develops • fever and infection develop

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

• Adults and children 2 to 12 years of age and older: Moisten a cotton pellet with 1 or 2 drops of the product and then apply to the cotton pellet on the applicable tooth. Avoid touching tissues other than the tooth cavity. Apply the dose not more than four times daily or as directed by a dentist or physician.

• Children 2 to 12 years of age: should be supervised in the use of this product. Children under 2 years of age: use only under the advice of a dentist or physician.

Other Information

- Do not purchase if package has been opened Store at 46 90°F
- Cap tightly to avoid evaporation

Inactive Ingredients:

Ammonium Glycyrrhizate, Flavor, PEG-400, PEG-3350, Sodium Saccharin Dihydrate, Sorbic Acid

Questions/Comments please call: 1 888 779 2877 Monday to Friday 9AM - 5PM EST

PAIN RELIEF

For toothaches

Distributed by Belmora LLC, 3033 Wilson Blvd. Suite 700 Arlington, VA 22201 www.anadentusa.com

Packaging



TOOTH RELIEF EUGENOL 1.2% GEL

For toothaches

Para dolor de muelas



AnaDent Gel Kanka para Niños/

Children's Kanka Gel





www.anadentusa.com

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Toothache Relief Agent %Zil lonagu3 Active Ingredient

Drug Facts

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dihidrato de sacarina de sodio, ácido sórbico

Ingredientes inactivos: Clicirizato de amonio, sabor, PEG-400, PEG-3350,

- m Tápelo firmemente para evitar la evaporación
- 4 "06-'34 ab siufsragmat snu s olanácem#A 🖿
- No compre el producto si el paquete ha sido abierto
 - Otra Información

Miños menores de 2 años: úsese solamente bajo el consejo de un dentista o un médico. ■ Miños de 2 a 12 años: deben ser supervisados durante el uso de este producto.

tocar otros tejidos que no sean la cavidad del ciente. Aplique la dosis no más de con 1 ó 2 gotas del producto y apliquela sobre el diente correspondiente. Eviñe

Mantener fuera del alcance de los niños. Si se traga el medicamento, busque ayuda médica o comuniquese con un Centro de Control de Envenenziniento de inmediato.

■ persiste la inflacción o si se presenta inflamación ■ flebre o infección Deje de usar el medicamento y pregúntele a un dentista o un médico si

■ durante más de 7 días ni con una dosis ■ mayor que la recomendada

■ NO LO TRAGUE, para evitar irritación ■ evite el contacto con los ojos naelo sofamente en dientes con dofor pulsante persistente Cuando use este producto

Plerta de Alergia: No usar si usted es alérgico al eugenol (aceite de clavo). Advertencias: Solo para uso externo.

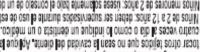
persistente y punzante.

USOS: Para el alivio temporal del dolor de dientes

Eugenal 1.2%. Agente Analgeico para el Dolor de Dientes otizòqor9 ovitaA ətnəibərpni

Drug Facts





■ Adultos y miños entre 2 y 12 años y mayores: Humedezca una bolita de algodón

DRUG FACTS TABLE

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ANADENT CHILDRENS KANKA GEL

eugenol gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:27854-178

Route of Administration DENTAL

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength
ELICENOL (LINIII, STOUT 7040MA (ELICENOL	LINIII. STOLI 7040M	ELICENOL	12 mg in 1 g

EUGENOL (UNII: 3T8H1794QW) (EUGENOL - UNII:3T8H1794QW) EUGENOL 12 mg in 1 g

Inactive Ingredients

•	
Ingredient Name	Strength
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBIC ACID (UNII: X045WJ989B)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:27854-178- 01	1 in 1 CARTON	11/08/2022	
1		7 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC monograph not final	part356	11/08/2022	

Labeler - Belmora LLC (112753244)

Revised: 11/2022 Belmora LLC