

**ANADENT KANKA GEL- benzocaine 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.*

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**AnaDent Kanka Gel**

**Drug Facts**

**Active Ingredient**

Benzocaine 20%

**Purpose**

oral pain reliever

**Uses**

- For the temporary relief of pain due to toothache
- To help protect against infection of minor oral irritation.

**Warnings**

**Methemoglobinemia warning:** use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. This can occur even if you have used this product before. Stop use and seek immediate medical attention if you or a child in your care develops:

- pale, gray, or blue colored skin (cyanosis)
- headache
- rapid heart rate
- shortness of breath
- dizziness or lightheadedness
- fatigue or lack of energy

**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
- for teething
- in children under 2 years of age

**Stop use and ask a dentist or doctor if**

- swelling, rash or fever develops
- irritation, pain or redness persists or worsens
- symptoms do not improve in 7 days
- allergic reaction occurs

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**

- Cut open tip of tube on score mark
- Adults and children 2 years of age and older: apply a small amount of product to the cavity and around the gum surrounding the teeth. Use up to 4 times daily or as directed by a dentist or doctor
- Children under 12 years of age should be supervised in the use of this product
- Children under 2 years of age: do not use

**Other Information**

- Do not use if tip is cut prior to opening
- This preparation is intended for use in cases of toothache, only as a temporary expedient until a dentist can be consulted
- Do not use continuously
- This formula will stay in place for extended duration of relief
- Avoid using toothpaste or drinking soft drinks or fruit juices for at least one hour after applying

**Inactive Ingredients:**

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

20% BENZOCAINE TO RELIEVE ORAL PAIN

COOLS GUM & RELIEVES IRRITATION

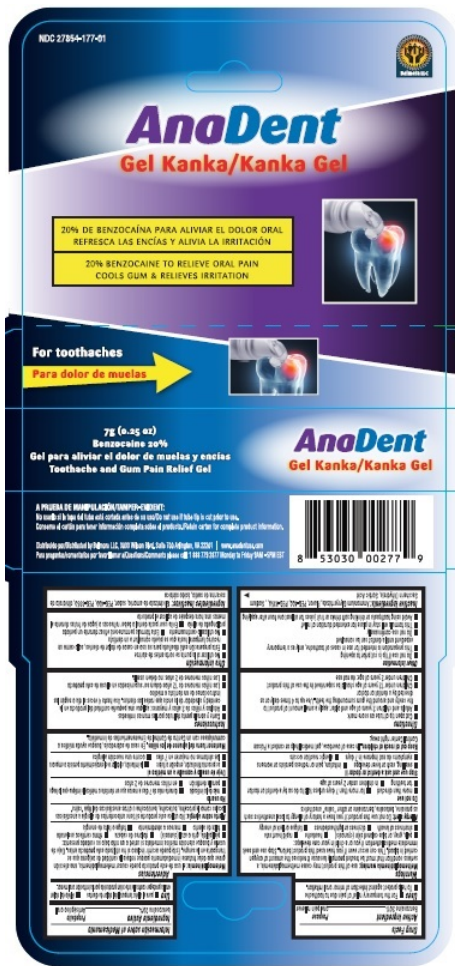
**For toothaches****Toothache and Gum pain Relief Gel****TAMPER-EVIDENT:**

Do not use if tube is cut prior to use.  
Retain carton for complete product information.

Distributed by Belmora LLC, 3033 Wilson Blvd. Suite 700 Arlington, VA 22201 |  
[www.anadentusa.com](http://www.anadentusa.com)

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

**Packaging**



**DRUG FACTS LABEL**

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**Información sobre el Medicamento**

Ingrediente Activo	Propósito
benzocaina 20%	Antiséptico oral

**Uso** ■ para el alivio temporal del dolor de dientes ■ Alivio del dolor oral a proteger contra la infección producida por la irritación oral menor.

**Advertencias**

**Metemoglobinemia:** el uso de este producto puede causar metemoglobinemia, una afección grave que debe tratarse inmediatamente porque reduce la cantidad de oxígeno que se transporta en la sangre. Esto puede ocurrir incluso si ha utilizado este producto antes. Deje de usarlo y busque atención médica inmediata si usted o un niño bajo su cuidado presenta:

- piel pálida, gris o azul (cianosis) ■ dolores de cabeza ■ ritmo cardíaco acelerado
- falta de aliento ■ mareos o aturdimiento ■ fatiga o falta de energía

**Alerta sobre alergia:** No utilice este producto si tiene antecedentes de alergia a anestésicos locales como la procaina, butacaina, benzocaina u otros anestésicos del tipo "caina"

**No usarlo**

- más de lo indicado ■ durante más de 7 días a menos que un dentista o médico le indique que lo haga
- para la dentición ■ en niños menores de 2 años

**Deje de usarlo y consulte a un médico si**

- se presenta hinchazón, erupción o fiebre ■ la irritación, el dolor o el enrojecimiento persiste o empeora
- los síntomas no mejoran en 7 días ■ ocurre una reacción alérgica

**Mantener fuera del alcance de los niños.** En caso de sobredosis, busque ayuda médica o comuníquese con un Centro de Control de Envenenamientos de inmediato.

**Instrucciones**

- Corte y abra la punta del tubo por las marcas indicadas
- Adultos y niños de 2 años y mayores: aplique una pequeña cantidad del producto en la cavidad y alrededor de la encía que rodea los dientes. Use hasta 4 veces al día o según las instrucciones de un dentista o médico
- Los niños menores de 12 años deben ser supervisados en el uso de este producto
- Los niños menores de 2 años: no deben usarlo.

**Otra información**

- No utilizar si la punta se corta antes de abrirse
- Esta preparación está diseñada para su uso en casos de dolor de dientes, solo como un recurso temporal hasta que se pueda consultar a un dentista
- No utilizarlo continuamente ■ Esta fórmula permanecerá eficaz durante un periodo prolongado de alivio ■ Evite usar pasta dental o beber refrescos o jugos de frutas durante al menos una hora después de aplicar el producto

**Ingredientes inactivos:** Glucirizado de amonio, sabor, PEG-400, PEG-3350, dihidrato de sacarina de sodio, ácido sórbico

**ANADENT KANKA GEL**

benzocaine gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:27854-177
<b>Route of Administration</b>	DENTAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>BENZOCAINE</b> (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	200 mg in 1 g

**Inactive Ingredients**

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

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:27854-177-01	1 in 1 CARTON	04/15/2022	
1		7 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	04/15/2022	

**Labeler** - BELMORA LLC (112753244)

Revised: 4/2022

BELMORA LLC