

**FINAFTA MULTIORAL- benzocaine spray**  
**Efficient Laboratories Inc.**

*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.*

-----

<b>Active Ingredients: (%)</b>	<b>Purpose</b>
Benzocaine USP 7.5% .....	Oral Anesthetic/Analgesic

**Purpose**

Oral Anesthetic/Analgesic

**Warnings: Do not exceed recommended dosage**

**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 the 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 prcaine, butacaine, bezocaine, or other "caine" anesthetics.

**Do not use**

- for teething
- in children under 2 years of age

**Consult a doctor promptly if:**

sore mouth symptoms do not improve in 7 days, or if irritation, pain, or redness persists or worsens. If sore throat is sever, persists for more than 2 days, is accompanied or followed by fever, headache, rash, swelling, nausea, or vomiting.

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

**If pregnant or breastfeeding,** ask a health professional before use.

**DIRECTIONS:**

For children over 12 years of age and Adults

- Apply Finafta® MultiOral Spray up to 4 times daily to affected areas of the mouth,

gums or mucus membranes (mouth and throat).

- Allow to remain in place at least 1 minute and then spit out.
- Close bottle tightly after each use.
- Children under 12 years of age: Do not use.

## USES

For the temporary relief of occasional minor irritation, pain, sore mouth, pain associated with canker sores or pain due to minor irritation of the mouth and gums cause by dentures or orthodontic appliances.

## Inactive ingredients:

Benzalkonium chloride, glycerin, methylparaben, peppermint oil, phosphoric acid, propylene glycol, propylparaben and purified water.

## QUESTIONS OR COMMENTS?

305-805-3456

Monday-Friday (9 a.m.- 5 p.m. EST)

www.efficientlabs.com


**FINAFTA**  
**MULTIORAL**  
**SPRAY**

**FINAFTA**  
**MultiOral**  
**SPRAY**

*Fast Acting relief of:*

- Sore Mouth
- Fever Blisters
- Minor irritation of the mouth & gums
- Pain due to minor dental procedures, dentures, or Orthodontic appliances


**ORAL ANESTÉSICO/ANALGÉSICO**



**Contiene Benzocaína Libre-de-Alcohol**

**Contiene Benzocaína Alcohol-Free**

Rev. Date: 04/18



0 00856 14782 9

**Drug Facts**

Active ingredient (%)	Purpose
Benzocaine 7.5%	Oral Anesthetic/Analgesic

**Uses** - For the temporary relief of occasional minor irritation, pain, sore mouth, pain associated with canker sores or pain due to minor irritation of the mouth and gums caused by dentures or orthodontic appliances.

**Warnings:** Do not exceed recommended dosage. Use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen that 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**  
• for teething  
• in children under 2 years of age

**Consult a doctor promptly if:**  
• sore mouth symptoms do not improve in 7 days, or if irritation, pain, or redness persists or worsens, if sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, swelling, nausea, or vomiting.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. If pregnant or breastfeeding, ask a health professional before use.

**Directions**  
• For children over 12 years of age and Adults - Apply Finafta® MultiOral Spray up to 4 times daily to affected areas of the mouth, gums or mucous membranes (mouth and throat). • Allow to remain in place at least 1 minute and then spit out. • Close bottle tightly after each use. • Children under 12 years of age: Do not use.

**Other information**  
• Do not store this product if safety seal is torn, broken, or missing. • Store between 15°-30°C (59°-86°F). • Keep box for information.


**Inactive ingredients**  
Benzalkonium chloride, glycerin, methylparaben, propylparaben, phosphoric acid, propylene glycol, propylparaben and purified water.

**Questions or comments?** (305) 805-3456  
Monday-Friday (9 a.m.-5 p.m.)  
www.efficientlabs.com

**EFFICIENT**  
LABORATORIES, INC.

**FINAFTA**  
**MultiOral**  
**SPRAY**

*Oral Anesthetic/Analgesic*  
**Benzocaine**



**2 FL. OZ.**

**Datos Farmacológicos**

Ingrediente activo (%)	Propósito
Benzocaína 7.5%	Anestésico/Analgésico Oral

**Usos** - Para el alivio temporal de una irritación leve ocasional, dolor en la boca, dolor asociado con aftas o dolor debido a irritación leve de la boca y las partes causado por dentaduras postizas o aparatos de ortodoncia.

**Advertencias:** No exceder la dosis recomendada. El uso de este producto puede causar metemoglobinemia, una afección grave que debe tratarse con prontitud porque reduce la cantidad de oxígeno en sangre. Esto puede ocurrir incluso si ha usado este producto anteriormente. Deje de usar y busque atención médica inmediata si usted o un niño en su cuidado desarrolla:  
• piel pálida, gris o azul (cianosis) • dolor de cabeza  
• frecuencia cardíaca rápida • dificultad para respirar  
• mareos o aturdimiento • fatiga o falta de energía

**Alerta de alergia** - No utilice este producto si usted tiene una historia de alergia a los anestésicos locales tales como procaina, butacaina, benzocaína, u otros anestésicos conteniendo el prefijo "caine". Personas con sensibilidad a la Benzocaína, no deben usar este producto.

**No use**  
• para la dentición  
• en niños menores de 2 años

**Consulte a un médico de inmediato si:**  
• Los síntomas de dolor en la boca no mejoran en 7 días, o si la irritación, el dolor o el enrojecimiento persisten o empeoran. Si el dolor de garganta es intenso, persiste durante más de 2 días, va acompañado o seguido de fiebre, dolor de cabeza, erupción cutánea, hinchazón, náuseas o vómitos.

**Mantenga fuera del alcance de los niños.** En caso de sobredosis, obtenga ayuda médica o comuníquese con un Centro de Control de Intoxicaciones de inmediato. Si está embarazada o amamantando, consulte a un profesional de la salud antes de usar.

**Instrucciones**  
Adultos y niños de 12 años en adelante: aplicar en el área afectada. Hacer gárgaras, distribuirlo en la boca, o permitir que permanezca en su lugar por lo menos 1 minuto y luego escupirlo. Use hasta 4 veces al día o en las áreas afectadas de la boca, antes o las membranas mucosas (boca y garganta). Cierre la botella herméticamente después de cada uso. No utilice en niños menores de 12 años de edad.

**Información adicional**  
• No aceptar este producto si el sello de seguridad está roto o falta.  
• Almacene entre 15°-30°F (59°-86°F).  
• Guarde la caja para instrucciones.

**Ingredientes Inactivos**  
Afeite de hierbabuena, ácido fórfórico, agua purificada, cloruro de benzalkonio, glicerina, metilparaben, propilparaben, aceite de menta, propilparaben, propilparaben.

**Preguntas o comentarios?** (305) 805-3456  
Lunes-Viernes (9 a.m.-5 p.m.)  
www.efficientlabs.com

Distributed by:  
Efficient Laboratories, Inc.  
Miami, FL 33166, MADE IN U.S.A.

Distribuido por:  
Efficient Laboratories, Inc.  
Miami, FL 33166, Hecho en U.S.A.

**FINAFTA MULTIORAL**

benzocaine spray

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58593-782
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>BENZOCAINE</b> (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	7.5 mg in 100 mL

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>PEPPERMINT OIL</b> (UNII: AV092KU4JH)	
<b>PHOSPHORIC ACID</b> (UNII: E4GA8884NN)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:58593-782-02	1 in 1 CARTON	09/01/2004	
1		59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part356	09/01/2004	

**Labeler** - Efficient Laboratories Inc. (969044932)

## Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Dextrum Laboratories Inc.		007392322	manufacture(58593-782)