

FINAFTA- ethyl alcohol, salicylic acid, benzocaine liquid
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.

Finafta

Active Ingredients: (%)	Purpose
Ethyl Alcohol 60% v/v.....	Anesthetic/Analgesic
Salicylic Acid 1% w/v.....	Anesthetic/Analgesic
Benzocaine USP 5% w/v.....	Anesthetic/Analgesic

Purpose

Anesthetic/Analgesic

Uses

For temporary relief of pain associated with canker sores

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 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.

Alcogol Warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whehter you should take slicylic acid or other pain reliever, fever reducer. Salicylic acid may cause stomach bleeding.

Flammable: Keep away from fire or flame.

Do not use

- for teething
- in children under 2 years of age

When using this prduct Do not use near eyes. Do not prolong usage unless directed by a doctor/dentist.

Stop use and ask a doctor promptly if sore mouth symptoms do not improve in 7 days or if irritation, pain or redness persists or worsens. If you sore throat 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.

Directions

Adults and children over 12 years of age apply to the affected area, mouth, gums or mucous membrane with the applicator provided, up to 4 times daily or as directed by a dentist or doctor. Remain in place at least 1 minute and then spit out. Do not rinse mouth after each use. Children under 12 years of age should be supervised in the use of the product. Do not use in children under 2 years of age.

Questions or comments?

305-805-3456

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

www.efficientlabs.com

Inactive Ingredients:

Propylene Glycol and Purified Water.

EFFICIENT **FINAFTA[®]**
Analgesic Liquid

*¡Ulceritas,
duelen!*

Alivio Instantáneo para su Boca y Encías

FINAFTA[®] *For instant relief of
the symptoms
of Canker Sores
& Cold Sores*

Anesthetic | Analgesic Liquid
Ethyl Alcohol
Salicylic Acid
Benzocaine

Instant Relief for the Mouth and Gums **0.5 fl.oz.**

FINAFTA
Anesthetic | Analgesic Liquid

FINAFTA Alivia los síntomas de las AFTAs, Fuegos y Ulceritas Bucleas
Líquido Anestésico | Analgésico

Alivio Instantáneo para su Boca y Encías

0.5 oz.fl.

Distributed by/Distribuido por:
Efficient Laboratories, Inc.
Miami, FL 33166. MADE IN U.S.A.
REV. 06/18



<p>¿Preguntas o Comentarios? (305) 805-3456 Lunes-Viernes (9 a.m.-5 p.m.)</p> <p>Ingredientes Inactivos Agua purificada y propileno glicol.</p> <p>de cada uso. talla. Cierre la botella herméticamente después de cada uso. Mantenga la caja para información. Sello de seguridad: no aceptar el premio de seguridad está roto o alado. Almacene entre 15° - 30° C (59° - 86° F). Finata es tolerable para las personas sensibles.</p> <p>Otra información Finata es tolerable para las personas sensibles.</p> <p>Datos Farmacológicos (Continúa)</p>	<p>Questions or comments? (305) 805-3456 Monday-Friday (9 a.m.-5 p.m.)</p> <p>Inactive ingredients Propylene glycol and purified water</p> <p>of each use. size. Close the bottle tightly after each use. Keep box for information. Tamper-evident: Do not accept if safety seal is broken or missing. Close the box if the seal is broken or missing. Store between 15° - 30°C (59° - 86°F). Finata is tolerable to iodine-sensitive individuals.</p> <p>Other information Finata is tolerable to iodine-sensitive individuals.</p> <p>Drug Facts (Continued)</p>
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<p>Datos Farmacológicos</p> <p>Propósito Alcohol Etilico 60% w/v Anestésico Oral Anestésico Oral Anestésico Oral Benzocaina 5% w/v</p> <p>Ingredientes activos (%)</p> <p>Usos • Para el alivio temporal del dolor asociado con las aftas.</p> <p>Advertencias Este producto puede causar metemoglobinemia. El uso de este producto puede causar metemoglobinemia, una condición grave que debe tratarse con prontitud porque reduce la cantidad de oxígeno en sangre. Esto puede ocurrir incluso si ha usado este producto anteriormente. Déle de usar y busque atención médica inmediata si usted o si un niño en su cuidado desearra: • piel pálida, gris o azul (cianosis) • dolor de cabeza • frecuencia cardíaca rápida • dificultad para respirar • mareos o aturdimiento</p> <p>Alerta de alergia • no use este producto si tiene un historial de alergia a anestésicos locales como procaina, butacaina, benzocaina u otros anestésicos "cana".</p> <p>Advertencia de alcohol: si consume 3 o más bebidas alcohólicas todos los días, pregúntele a su médico si debe tomar ácido salicílico u otro analgésico, reductor de fiebre, El ácido salicílico puede causar sangrado estomacal.</p> <p>Infamable: Mantener alejado del fuego o la llama para evitar incendios.</p> <p>No use • para la dentición • en niños menores de 2 años</p> <p>Cuando use este producto No lo use cerca de los ojos. No prolongue el uso a menos que lo indique un médico/dentista.</p> <p>Para el uso y consulte a un médico de inmediato si los síntomas de dolor en la boca no mejoran en 7 días o si hay irritación, el dolor o el enrojecimiento persisten o empeoran. Si el dolor de garganta va acompañado o seguido de fiebre, vómitos, dolor de cabeza, sarpullido, hinchazón, náuseas o</p> <p>Mantener fuera del alcance de los niños. En caso de sobredosis, obtenga ayuda médica o comuníquese con un Centro de Control de Intoxicaciones de inmediato.</p> <p>Indicaciones de uso • Adultos y niños mayores a 12 años de edad: aplicar a la zona afectada, la boca, las encías o la membrana mucosa con el aplicador provisto, hasta 4 veces al día o según lo indique un dentista o médico. Manténgalo en su lugar al menos 1 minuto y luego escúpalo. No enjuagar la boca. Niños entre 2 y 12 años de edad: Consultar a un médico. Supervise a los niños menores de 12 años al usar este producto. Niños menores a 2 años de edad: No lo use.</p> <p>Direcciones • Adults and children over 12 years of age apply to the affected area, mouth, gums or mucous membrane with the applicator provided, up to 4 times daily or as directed by a dentist or doctor. Remain in place at least 1 minute and then spit out. Do not rinse mouth after each use. Children between 2 and 12 years of age: consult a doctor. Children under 12 years of age should be supervised in the use of the product. Do not use in children under 2 years of age.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p> <p>When using this product Do not use near eyes. Do not prolong usage unless directed by a doctor/dentist.</p> <p>Stop use and ask 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 accompanied or followed by fever, headache, rash, swelling, nausea, or vomiting.</p> <p>Alcohol Warning: If you consume 3 or more alcohol drinks every day, ask your doctor whether you should take salicylic acid or other pain reliever. Fever reducer. Salicylic Acid may cause stomach bleeding.</p> <p>Flammable: Keep away from fire or flame.</p> <p>Do not use • for teething • in children under 2 years of age</p> <p>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 • dizziness or breath • rapid heart rate (cyanosis) • headache • rapid heart rate • shortness of breath • dizziness or lightheadedness • fatigue or lack of energy</p> <p>Allergy alert • do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine, or other "cane" anesthetics.</p> <p>Alcohol Warning: If you consume 3 or more alcohol drinks every day, ask your doctor whether you should take salicylic acid or other pain reliever. Fever reducer. Salicylic Acid may cause stomach bleeding.</p> <p>Flammable: Keep away from fire or flame.</p> <p>Do not use • for teething • in children under 2 years of age</p> <p>When using this product Do not use near eyes. 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In case of overdose, get medical help or contact a Poison Control Center right away.</p> <p>Children under 2 years of age: Do not use in children under 2 years of age.</p>	<p>Drug Facts</p> <p>Active ingredients (%) Benzocaine 5% w/v Sulicylic Acid 1% w/v Ethyl Alcohol 60% w/v Oral Anesthetic Oral Anesthetic Oral Anesthetic</p> <p>Purpose For temporary relief of pain associated with canker sores.</p> <p>Uses • For temporary relief of pain associated with canker sores.</p> <p>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. 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FINAFTA
ethyl alcohol, salicylic acid, benzocaine liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58593-780
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	60 mL in 100 mL
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	1 mg in 100 mL
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	5 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58593-780-15	15 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	10/01/1991	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	10/01/1991	06/01/2026

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

Name	Address	ID/FEI	Business Operations
Dextrum Laboratories Inc.		007392322	manufacture(58593-780)

Revised: 8/2023

Efficient Laboratories Inc.