

FINAFTA- benzocaine, glycerin liquid
Efficient Laboratories Inc.

Finafta

Active Ingredients: (%) Purpose

Benzocaine USP 5%.....Oral Anesthetic

Glycerin 33%Oral Demulcen

Purpose

Oral Anesthetic

Oral Demulcen

Uses

For temporary relief of pain associated with canker sores

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 procaine, butacaine, benzocaine, or other "caine" anesthetics.

Do not use this product for more than 7 days unless directed by a dentist or doctor. If sore mouth symptoms do not improve in 7 days; if irritation, pain, or redness persists or worsens; or if swelling, rash or fever develops, see your dentist or doctor promptly.

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 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.

Questions or comments?

305-805-3456

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

www.efficientlabs.com

Inactive Ingredients:

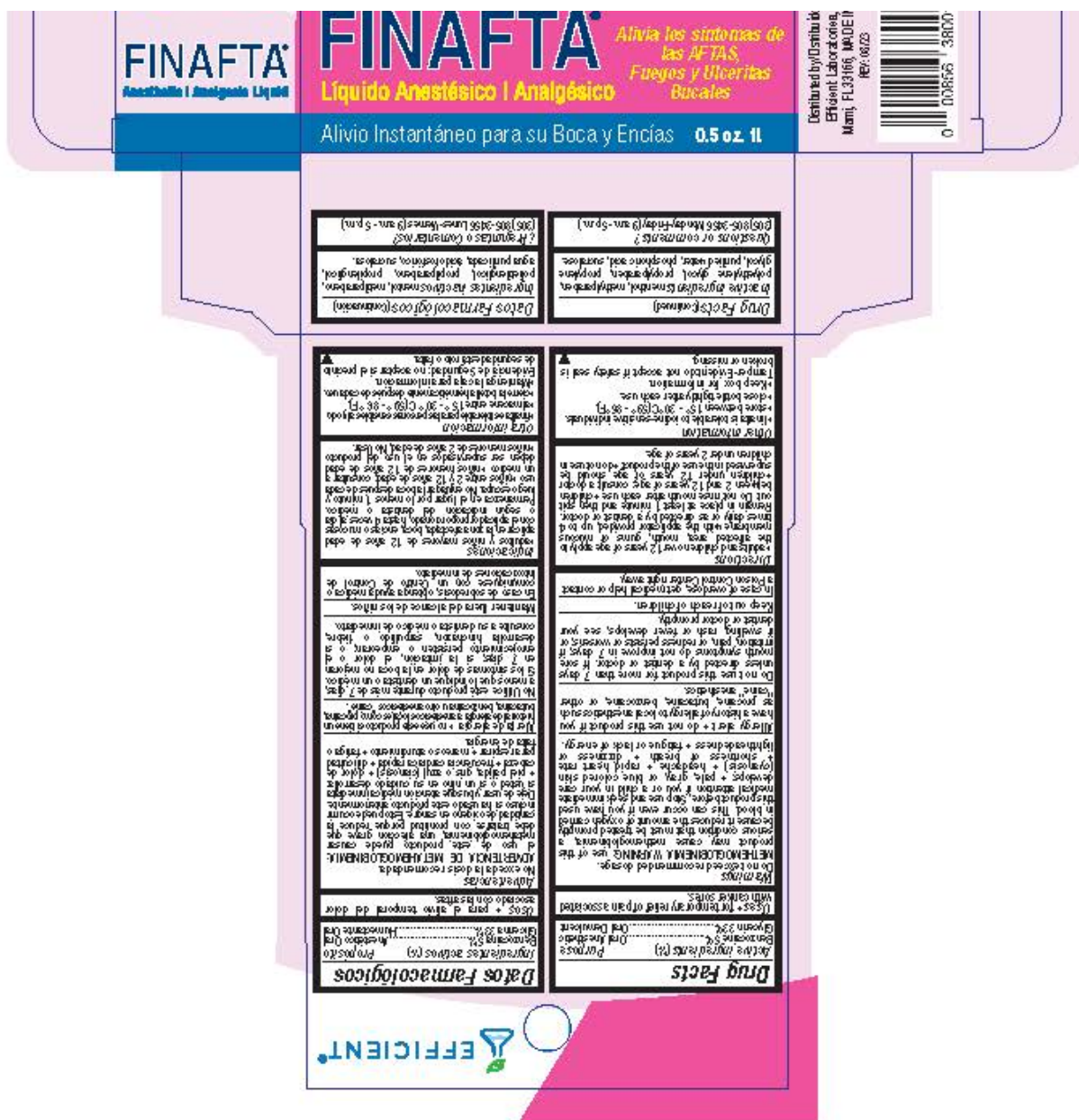
menthol, methylparaben, polyethylene glycol, propylparaben, propylene glycol, purified water, phosphoric acid, sucralose.

Other Information

- finafta is tolerable to iodine-sensitive individuals.
- store between 15° - 30°C (59° - 86°F).
- close bottle tightly after each use.
- Keep box for information.

Tamper-Evident: do not accept if safety seal is broken or missing.





FINAFTA

benzocaine, glycerin liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58593-783
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	5 mg in 100 mL
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	33 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
MENTHOL (UNII: L7T10EIP3A)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58593-783-15	15 mL in 1 BOTTLE, WTH APPLICATOR; Type 0: Not a Combination Product	09/15/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	09/15/2023	

Labeler - Efficient Laboratories Inc. (969044932)

Revised: 10/2024

Efficient Laboratories Inc.