FINAFTA MULTIORAL- benzocaine spray
Dextrum Laboratories Inc.

Finafta Multioral

Active Ingredients: (%) **Purpose**

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 mthemoglobinemia, a serious condition that must be treated promptyly 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 enegry

Allegry 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 othodontic applicances.

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

benzocaine spray

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:65852-001
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65852-001-02	1 in 1 CARTON	09/01/2004	
1		59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	09/01/2004	

Labeler - Dextrum Laboratories Inc. (007392322)

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