

KOLORZ - sodium fluoride aerosol, foam
Medical Products Laboratories, Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).

kolorz Sixty Second Fluoride Foam Blue Raspberry

Dosage and Administration

Shake can vigorously before each use. Turn can completely upside down to dispense. Point can towards fluoride applicator tray and slowly press the nozzle to fill tray. Use one press per arch, as foam will expand slightly to fill the tray. Dry tooth surface and insert tray(s) in mouth. Have patient bite down lightly but firmly for 1 to 4 minutes. Remove tray(s) and have patient expectorate excess. Instruct patient not to eat, drink, or rinse for at least 30 minutes after application.

Instructions For Use

The first time you dispense from a new bottle, gently lift upward on the nozzle to break the protective shipping tab (thin plastic tab located adjacent to "trigger"). If this tab is not broken, there could be an initial surge of foam from the dispenser.

CONTAINS

Sodium Fluoride in a proprietary acidulated phosphate flavored foam base. 1.23% Fluoride Ion is available from 2.72% Sodium Fluoride. Does not contain chlorofluorocarbon propellant. Sweetened with Sucralose. Does not contain Aspartame or Saccharin. Gluten free.

WARNING Avoid spraying toward open flame. Contents under pressure. Do not puncture or incinerate. Keep out of reach children. Store between 55-80 F. Keep from freezing.

CAUTION

For professional use only. Federal U.S.A. Law prohibits dispensing without prescription. Shake well before each use.

How Supplied

Kolorz Sixty Second Fluoride Foam is available in 4.4 oz. (125g) can and do not contain chlorofluorocarbon propellant.

INDICATIONS

For the topical application of fluoride to aid in the protection against dental caries. Shake can thoroughly for at least 30 seconds before each use. Hold can completely upside down to dispense. See package insert for dosage information.



Distributed by DMG America
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Rev. 9/09

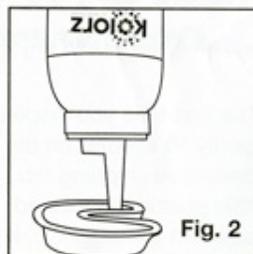
P/N 002-1006

Dosage and Administration:

1. Shake can vigorously before each use. (Fig. 1)



2. Turn can completely upside down to dispense. Point can towards fluoride applicator tray and slowly press the nozzle to fill tray. Use one press per arch, as foam will expand slightly to fill the tray. (Fig. 2)



3. Dry tooth surface and insert tray(s) in mouth.
4. For Kolorz Sixty Second Fluoride Foam: Have patient bite down lightly but firmly for 1 to 4 minutes; For Kolorz Neutral Fluoride Foam: Have patient bite down lightly but firmly for 4 minutes.



By DMG America
Instructions For Use

Kolorz Sixty Second Fluoride Foam Kolorz Neutral Fluoride Foam

The first time you dispense from a new bottle, gently lift upward on the nozzle to break the protective shipping tab (thin plastic tab located adjacent to "trigger"). If this tab is not broken, there could be an initial surge of foam from the dispenser.



5. Remove tray(s) and have patient expectorate excess
6. Instruct patient not to eat, drink, or rinse for at least 30 minutes after application.

How Supplied: Both Kolorz Sixty Second Fluoride Foam and Kolorz Neutral Fluoride Foam are available in 4.4oz. (125g) cans and do not contain chlorofluorocarbon propellant.

Caution: For professional use only. Federal U.S.A. Law prohibits dispensing without prescription.

Warning: Contents under pressure. Do not puncture or incinerate. Store between 55-80° F. Keep from freezing.

Best Taste...
Guaranteed!



Sixty
Second
Fluoride Foam
Blue Raspberry

APF Topical Fluoride
Acidulated Phosphate Fluoride
1.23% Fluoride Ion

GLUTEN FREE!

Contains
XYLITOL

CAUTION:
For professional use only.
Shake well before each use.

NET WT. 4.4 OZ (125g)

INDICATIONS:

For the topical application of fluoride to aid in the protection against dental caries.

Shake can thoroughly for at least 30 seconds before each use. Hold can completely upside down to dispense. See package insert for dosage information.



CONTAINS:

Sodium Fluoride in a proprietary acidulated phosphate flavored foam base. 1.23% Fluoride Ion is available from 2.72% Sodium Fluoride. Does not contain chlorofluorocarbon propellant.

Sweetened with Sucralose. Does not contain Aspartame or Saccharin. Gluten free.

WARNING:

Avoid spraying toward open flame. Contents under pressure. Do not puncture or incinerate. Keep out of reach of children. Store between 55-80° F. Keep from freezing.

EMERGENCY RESPONSE:
Call Infotrac 1-800-535-5053



Made in USA
Distributed by: DMG America LLC, 242 South Dean Street
Englewood, NJ 07631, 800-662-6383
www.dmg-america.com Rev. 4/09

RE-ORDER #766204

392411



KOLORZ

sodium fluoride aerosol, foam

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:10733-372
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (Fluoride ion - UNII:Q80VPU408O)	SODIUM FLUORIDE	27.2 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XYLITOL (UNII: VCQ006KQ1E)	
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	
BETAINE (UNII: 3SCV180C9W)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BERRY (Mixed Berry Flavor)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10733-372-00	6 in 1 BOX		
1		125 g in 1 CAN		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/01/2007	

Labeler - Medical Products Laboratories, Inc. (002290302)**Registrant** - Medical Products Laboratories, Inc. (002290302)**Establishment**

Name	Address	ID/FEI	Business Operations
Medical Products Laboratories, Inc.		002290302	analysis, manufacture, label, pack

Revised: 3/2011

Medical Products Laboratories, Inc.