

KOLORZ NEUTRAL FLUORIDE FOAM TRIPLE MINT- sodium fluoride aerosol, foam
DMG AMERICA, LLC

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[®] NEUTRAL Fluoride Foam

INDICATIONS

For the topical application of fluoride in a neutral base to aid in the protection against dental caries. Ideal for patients with extensive esthetic restorations and/or intolerance to acidic fluorides, Kolorz[®] Neutral Foam requires a 4-minute application.

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 neutral flavored foam base. 0.9% Fluoride Ion from 2% Sodium Fluoride at a neutral pH. This product 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. 4/13

RE-ORDER #766205

kolorz®

By DMG America

Instructions For Use

Kolorz Sixty Second Fluoride Foam

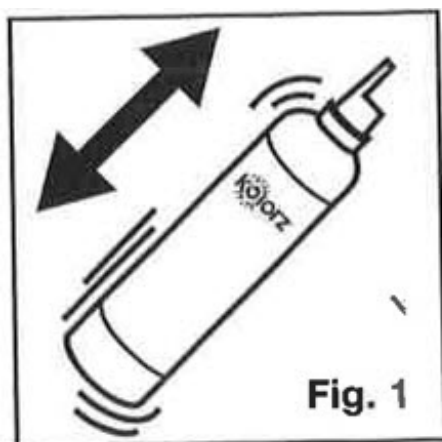
Kolorz Neutral Fluoride Foam

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.

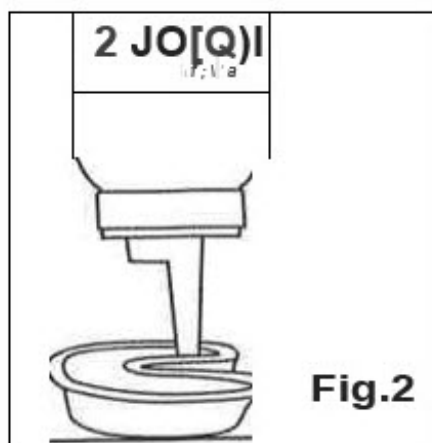


Dosage and Administration:

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.
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.

Distributed by DMG America
 242 South Dean Street
 Englewood, NJ 07631 USA
 Tel: 201-894-5505
 Fax: 201-894-0213
www.dmg-america.com

PRINCIPAL DISPLAY PANEL - 125 g Can Carton

Best Taste...

Guaranteed!

kolorz[®]

NEUTRAL

Fluoride Foam

Triple Mint

Neutral Sodium Fluoride

Contains 2.0% Sodium Fluoride

(0.9% Fluoride Ion)

GLUTEN FREE!

Contains

XYLITOL

CAUTION:

For professional use only.

Store at room temperature.

Shake well before each use.

NET WT. 4.4 OZ (125g)



NEUTRAL
Triple Mint
Fluoride Foam
Neutral Sodium Fluoride

Best Taste...
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★D03376620500★



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Fluoride Foam
Triple Mint

Neutral Sodium Fluoride
Contains 2.0% Sodium Fluoride
(0.9% Fluoride Ion)

GLUTEN FREE!

Contains
XYLITOL

CAUTION:
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Shake well before each use.



NET WT. 4.4 OZ (125g)



NEUTRAL
Fluoride Foam
Triple Mint

Neutral Sodium Fluoride
Contains 2.0% Sodium Fluoride
(0.9% Fluoride Ion)

GLUTEN FREE!

Contains
XYLITOL

CAUTION:
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NET WT. 4.4 OZ (125g)



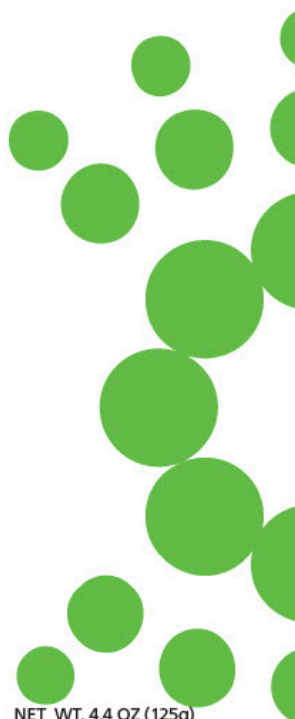
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Fluoride Foam
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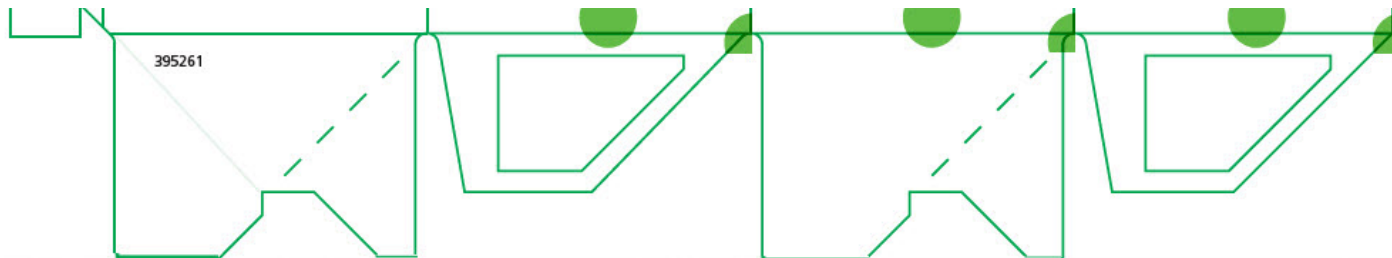
GLUTEN FREE!

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NET WT. 4.4 OZ (125g)



KOLORZ NEUTRAL FLUORIDE FOAM TRIPLE MINT

sodium fluoride aerosol, foam

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:25047-765
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	0.9 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT (TRIPLE MINT)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:25047-765-44	125 g in 1 CAN; Type 0: Not a Combination Product	11/22/2006	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		11/22/2006	

Labeler - DMG AMERICA, LLC (106792427)

Establishment

Name	Address	ID/FEI	Business Operations
Medical Products Laboratories, Inc.		002290302	MANUFACTURE(25047-765) , PACK(25047-765) , LABEL(25047-765)

Revised: 10/2021

DMG AMERICA, LLC