KOLORZ SIXTY SECOND FLUORIDE CHERRY CHEESECAKE- sodium fluoride gel KOLORZ SIXTY SECOND FLUORIDE PINA COLADA- sodium fluoride gel KOLORZ SIXTY SECOND FLUORIDE TRIPLE MINT- sodium fluoride gel KOLORZ SIXTY SECOND FLUORIDE BLUE RASPBERRY- sodium fluoride gel KOLORZ SIXTY SECOND FLUORIDE COTTON CANDY- sodium fluoride gel 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® Sixty Second Fluoride Gel

INDICATIONS

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

DOSAGE & ADMINISTRATION

Fill fluoride tray(s) 1/3 full with gel. Dry tooth surface and insert tray(s) in mouth. Have patient bite down for 60 seconds (or up to 4 minutes). Slight chewing motion provides interproximal coverage. Remove tray(s) and have patient expectorate excess gel. Advise patient not to eat, drink or rinse for 30 minutes.

CONTAINS

Sodium Fluoride in a proprietary acidulated phosphate flavored gel base. 1.23% Fluoride Ion from 2.72% Sodium Fluoride.

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

WARNING

Keep out of reach of children. Do not swallow. If dosage or less than 100mg is ingested, contact poison control.

Store between 68-77° F. Keep from freezing.

Contains FD&C Blue #1.

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 #777304 392415

PRINCIPAL DISPLAY PANEL - 480 ml Bottle Label - Cherry Cheesecake

Best Taste...

Guaranteed!

kolorz®

Sixty

Second

Fluoride Gel

Cherry Cheesecake

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. 16 OZ (480ml)

INDICATIONS:

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

DOSAGE & ADMINISTRATION:

Fill fluoride tray(s) 1/3 full with gel. Dry tooth surface and insert tray(s) in mouth. Have patient bite down for 60 seconds (or up to 4 minutes). Slight chewing motion provides interproximal coverage. Remove tray(s) and have patient expectorate excess gel. Advise patient not to eat, drink or rinse for 30 minutes.

CONTAINS:

Sodium Fluoride in a proprietary acidulated phosphate flavored gel base. 1.23% Fluoride Ion from 2.72% Sodium Fluoride.

Sweetened with Sucralose, Does not contain Aspartame or Saccharin, Gluten Free.

WARNING:

Keep out of reach of children. Do not swallow. If dosage or less than 100mg is ingested, contact poison control.

Store between 68-77° F. Keep from freezing.

Contains F&C Red #40 and D&C Red #33.

EMERGENCY RESPONSE:

Cal Infotrac 1-800-535-5053



Made in USA

Distributed by: DMG America LLC, 242 South Dean Street Englewood, NJ 07631, 800-662-6383

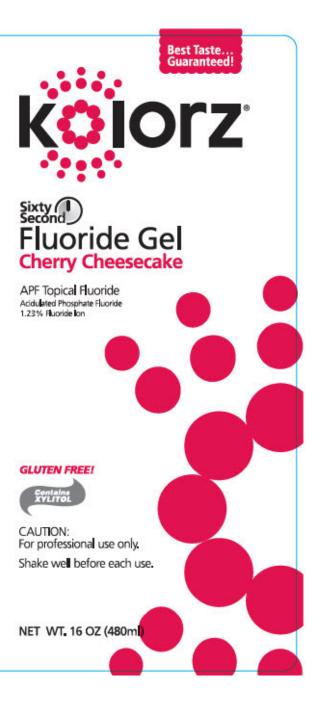
www.dmg-america.com

RE-ORDER #777302

392418

Rev. 4/09





PRINCIPAL DISPLAY PANEL - 480 ml Bottle Label - Piña Colada

Best Taste...
Guaranteed!

kolorz®

Sixty Second Fluoride Gel Piña Colada

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. 16 OZ (480ml)

INDICATIONS:

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

DOSAGE & ADMINISTRATION:

Fill fluoride tray(s) 1/3 full with gel. Dry tooth surface and insert tray(s) in mouth. Have patient bite down for 60 seconds (or up to 4 minutes). Slight chewing motion provides interproximal coverage. Remove tray(s) and have patient expectorate excess gel. Advise patient not to eat, drink or rinse for 30 minutes.

CONTAINS:

Sodium Fluoride in a proprietary acidulated phosphate flavored gel base. 1.23% Fluoride Ion from 2.72% Sodium Fluoride.

Sweetened with Sucralose. Does not contain Aspartame or Saccharin, Gluten Free.

WARNING:

Keep out of reach of children, Do not swallow, If dosage or less than 100mg is ingested, contact poison control.

Store between 68-77° F. Keep from freezing.

EMERGENCY RESPONSE:

Cal Infotrac 1-800-535-5053



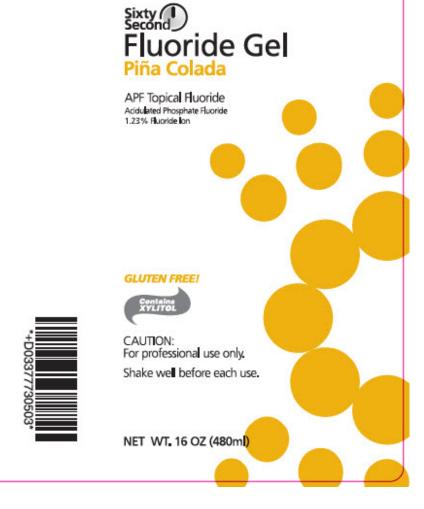
Made in USA

Distributed by: DMG America LLC, 242 South Dean Street Englewood, NJ 07631, 800-662-6383 Rev. 4/09

www.dmg-america.com

RE-ORDER #777305

392419



Best Taste... Guaranteed!

Olorz

PRINCIPAL DISPLAY PANEL - 480 ml Bottle Label - Triple Mint

Best Taste... Guaranteed!

kolorz®

Sixty Second Fluoride Gel Triple Mint

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. 16 OZ (480ml)

INDICATIONS:

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

DOSAGE & ADMINISTRATION:

Fill fluoride tray(s) 1/3 full with gel. Dry tooth surface and insert tray(s) in mouth. Have patient bite down for 60 seconds (or up to 4 minutes), Slight chewing motion provides interproximal coverage. Remove tray(s) and have patient expectorate excess gel. Advise patient not to eat, drink or rinse for 30 minutes.

CONTAINS:

Sodium Fluoride in a proprietary acidulated phosphate flavored gel base, 1.23% Fluoride Ion from 2.72% Sodium

Sweetened with Sucralose. Does not contain Aspartame or Saccharin, Gluten Free.

WARNING:

Keep out of reach of children, Do not swallow, If dosage or less than 100mg is ingested, contact poison control.

Store between 68-77° F. Keep from freezing.

FD&C Blue #1, Yellow #5

EMERGENCY RESPONSE:

Call Infotrac 1-800-535-5053

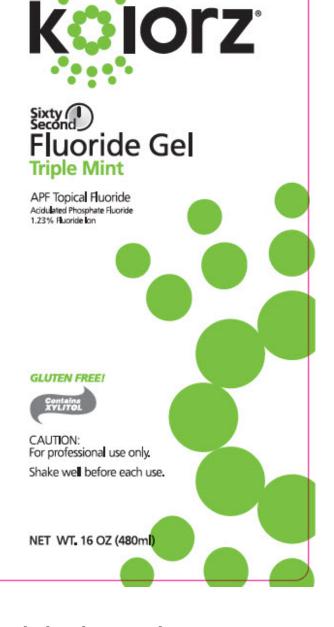


Made in USA Distributed by: DMG America LLC, 242 South Dean Street Englewood, NJ 07631, 800-662-6383 Rev. 4/09 www.dmg-america.com

RE-ORDER #777301

392420





Best Taste... Guaranteed!

PRINCIPAL DISPLAY PANEL - 480 ml Bottle Label - Blue Raspberry

Best Taste... Guaranteed!

kolorz®

Sixty Second Fluoride Gel 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. 16 OZ (480ml)

INDICATIONS:

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

DOSAGE & ADMINISTRATION:

Fill fluoride tray(s) 1/3 full with gel. Dry tooth surface and insert tray(s) in mouth. Have patient bite down for 60 seconds (or up to 4 minutes). Slight chewing motion provides interproximal coverage. Remove tray(s) and have patient expectorate excess gel. Advise patient not to eat, drink or rinse for 30 minutes.

CONTAINS:

Sodium Fluoride in a proprietary acidulated phosphate flavored gel base. 1.23% Fluoride Ion from 2.72% Sodium Fluoride.

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

WARNING:

Keep out of reach of children. Do not swallow. If dosage or less than 100mg is ingested, contact poison control.

Store between 68-77° F. Keep from freezing.

Contains FD&C Blue #1.

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

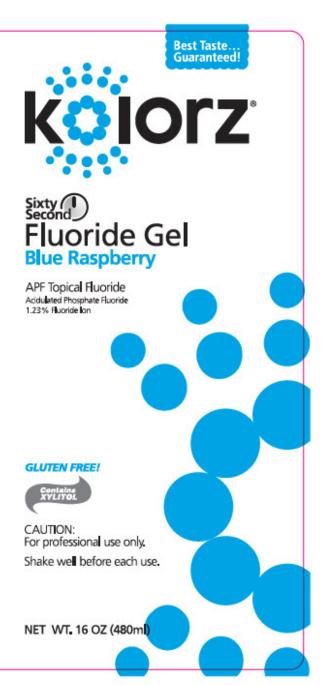
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RE-ORDER #777304

392416

Rev. 4/09





PRINCIPAL DISPLAY PANEL - 480 ml Bottle Label - Cotton Candy

Best Taste...
Guaranteed!

kolorz®

Sixty Second Fluoride Gel Cotton Candy

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. 16 OZ (480ml)

INDICATIONS:

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

DOSAGE & ADMINISTRATION:

Fill fluoride tray(s) 1/3 full with gel. Dry tooth surface and insert tray(s) in mouth. Have patient bite down for 60 seconds (or up to 4 minutes). Slight chewing motion provides interproximal coverage. Remove tray(s) and have patient expectorate excess gel. Advise patient not to eat, drink or rinse for 30 minutes.

CONTAINS:

Sodium Fluoride in a proprietary acidulated phosphate flavored gel base. 1.23% Fluoride Ion from 2.72% Sodium Fluoride.

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

WARNING:

Keep out of reach of children. Do not swallow. If dosage or less than 100mg is ingested, contact poison control.

Store between 68-77° F. Keep from freezing.

Contains D&C Red #33.

EMERGENCY RESPONSE:

Cal 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 #777303

392417







KOLORZ SIXTY SECOND FLUORIDE CHERRY CHEESECAKE

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:25047-772
Route of Administration	DENTAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII: Q80VPU4080)	SODIUM FLUORIDE	12.3 mg in 1 mL	

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			
XYLITOL (UNII: VCQ006KQ1E)			
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)			

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	CHERRY (CHERRY CHEESECAKE)	Imprint Code	
Contains			

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:25047-772- 16	480 mL in 1 BOTTLE; 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	

KOLORZ SIXTY SECOND FLUORIDE PINA COLADA

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:25047-775
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	SODIUM FLUORIDE	12.3 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

XYLITOL (UNII: VCQ006KQ1E) COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)	-1
II COCAMIDOPROPYL RETAINE (LINII) 5000 F3011KX)	

Product Characteristics				
Color		Score		
Shape		Size		
Flavor	PINEAPPLE (PIÑA COLADA)	Imprint Code		
Contains				

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:25047-775- 16	480 mL in 1 BOTTLE; 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	
OTHER			

KOLORZ SIXTY SECOND FLUORIDE TRIPLE MINT

sodium fluoride gel

Product Information				
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:25047-771	
Route of Administration	DENTAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	12.3 mg in 1 mL	

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
XYLITOL (UNII: VCQ006KQ1E)				
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)				

Product Characteristics

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

ı	Packaging				
	# Item	Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:25		80 mL in 1 BOTTLE; 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	

KOLORZ SIXTY SECOND FLUORIDE BLUE RASPBERRY

Product Information				
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:25047-774	
Route of Administration	DENTAL			

l	Active Ingredient/Active Moiety			
l	Ingredient Name	Basis of Strength	Strength	
	SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	12.3 mg in 1 mL	

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
SUCRALOSE (UNII: 96K6UQ3Z D4)				
XYLITOL (UNII: VCQ006KQ1E)				
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)				

Product Characteristics				
Color		Score		
Shape		Size		
Flavor	RASPBERRY (BLUE RASPBERRY)	Imprint Code		
Contains				

Packaging				
#	tem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:25047-774- 16	480 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/22/2006	

Marketing Information			
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
	11/22/2006		
	Application Number or Monograph	Application Number or Monograph Marketing Start Citation Date	

KOLORZ SIXTY SECOND FLUORIDE COTTON CANDY

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:25047-773
Route of Administration	DENTAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII: Q80VPU408O)	SODIUM FLUORIDE	12.3 mg in 1 mL	

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			
XYLITOL (UNII: VCQ006KQ1E)			
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)			

Product Characteristics		
Color		Score
Shape		Size
Flavor	COTTON CANDY (COTTON CANDY)	Imprint Code
Contains		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date

	Product 180TTLE; Type 0: Not a Combination	11/22/2006	
Marketing I	nformation		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Marketing	Application Number or Monograph	_	

Labeler - DMG AMERICA, LLC (106792427)

Establishment			
Name	Address	ID/FEI	Business Operations
Medical Products Laboratories, Inc.			MANUFACTURE(25047-771, 25047-772, 25047-773, 25047-774, 25047-775), PACK(25047-771, 25047-772, 25047-773, 25047-774, 25047-775), LABEL(25047-771, 25047-772, 25047-774, 25047-775)

Revised: 3/2019 DMG AMERICA, LLC