

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)

Best Taste...
Guaranteed!

kolorz[®]

Sixty
Second
Fluoride Gel
Cherry Cheesecake

APF Topical Fluoride
Acidulated Phosphate Fluoride
1.23% Fluoride Ion

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:

Call Infotrac 1-800-535-5053

kolorz

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RE-ORDER #777302

392418



GLUTEN FREE!

Contains
XYLITOL

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

NET WT. 16 OZ (480ml)

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:

Call Infotrac 1-800-535-5053



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RE-ORDER #777305

392419



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)

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)

Best Taste...
Guaranteed!

kolorz[®]

Sixty
Second
Fluoride Gel
Triple Mint

APF Topical Fluoride
Acidulated Phosphate Fluoride
1.23% Fluoride Ion

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.

FD&C Blue #1, Yellow #5

EMERGENCY RESPONSE:

Call Infotrac 1-800-535-5053

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www.dmg-america.com Rev. 4/09

RE-ORDER #777301

392420



GLUTEN FREE!

Contains
XYLITOL

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

NET WT. 16 OZ (480ml)

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



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Rev. 4/09

RE-ORDER #777304

392416



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)

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.

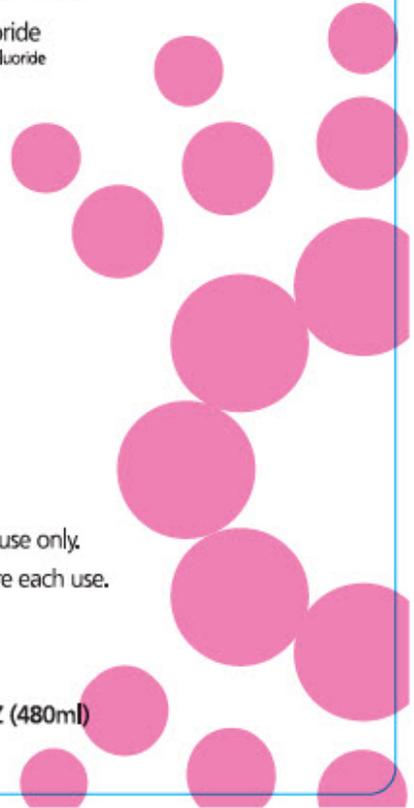
NET WT. 16 OZ (480ml)

Best Taste...
Guaranteed!



Sixty Second Fluoride Gel Cotton Candy

APF Topical Fluoride
Acidulated Phosphate Fluoride
1.23% Fluoride Ion



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:

Call Infotrac 1-800-535-5053



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RE-ORDER #777303

392417



GLUTEN FREE!



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

NET WT. 16 OZ (480ml)

KOLORZ SIXTY SECOND FLUORIDE CHERRY CHEESECAKE

sodium fluoride gel

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: 5OCF3O11KX) | |

Product Characteristics

| | | | |
|-----------------|----------------------------|---------------------|--|
| Color | | Score | |
| Shape | | Size | |
| Flavor | CHERRY (CHERRY CHEESECAKE) | Imprint Code | |
| Contains | | | |

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

sodium fluoride gel

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: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: 5OCF3O11KX) | |

Product Characteristics

| | | | |
|-----------------|-------------------------|---------------------|--|
| Color | | Score | |
| Shape | | Size | |
| Flavor | PINEAPPLE (PIÑA COLADA) | Imprint Code | |
| Contains | | | |

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 | |

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: 5OCF3O11KX) | |

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:25047-771-16 | 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 BLUE RASPBERRY

sodium fluoride gel

Product Information

| | | | |
|--------------------------------|-------------------------|---------------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:25047-774 |
| 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: 5OCF3O11KX) | |

Product Characteristics

| | | | |
|-----------------|----------------------------|---------------------|--|
| Color | | Score | |
| Shape | | Size | |
| Flavor | RASPBERRY (BLUE RASPBERRY) | Imprint Code | |
| Contains | | | |

Packaging

| # | Item 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

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

KOLORZ SIXTY SECOND FLUORIDE COTTON CANDY

sodium fluoride gel

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: 5OCF3011KX) | |

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 |
|---|-----------|---------------------|----------------------|--------------------|
|---|-----------|---------------------|----------------------|--------------------|

| | | | | |
|----------|------------------|---|------------|--|
| 1 | NDC:25047-773-16 | 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 | |

Labeler - DMG AMERICA, LLC (106792427)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------|---------|-----------|--|
| KEYSTONE INDUSTRIES | | 014769301 | MANUFACTURE(25047-771, 25047-772, 25047-773, 25047-774, 25047-775) |

Revised: 3/2019

DMG AMERICA, LLC