

GEL-KAM MINT- stannous fluoride gel, dentifrice
GEL-KAM FRUIT AND BERRY- stannous fluoride gel, dentifrice
Colgate Oral Pharmaceuticals, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Gel-Kam®

Drug Facts

Active ingredient

Stannous fluoride 0.4% (w/w)

Purposes

Anticavity/Sensitivity Relief

Uses

- helps protect against cavities
- builds increasing protection against painful sensitivity of the teeth to cold, heat, acids, sweets or contact

Warnings

Do not use this product longer than four weeks for sensitive teeth unless recommended by a dentist or physician.

Stop use and ask a doctor if problem persists or worsens. Sensitive teeth may indicate a serious problem that may need prompt care by a dentist.

Keep out of reach of children. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

- adults and children 12 years of age or older: use after regular brushing and flossing
- shake excess water from your toothbrush and cover bristles with gel
- brush thoroughly
- keep on your teeth for one minute and then spit out
- do not swallow
- do not rinse, eat or drink for 30 minutes
- use once a day for cavity protection
- use twice a day (morning and evening) for sensitivity relief or as recommended by a dentist or physician
- make sure all sensitive areas are covered by using a toothbrush or a cotton swab
- supervise children until capable of using without supervision
- children under 12 years of age: consult a dentist or physician

Other information

- this is a fluoride preventive treatment gel, not a toothpaste. Read directions carefully before use

- this product may produce surface staining of the teeth Adequate toothbrushing may prevent these stains which are not harmful or permanent and may be removed by your dentist
- do not use if embossed seal on tube is broken or missing
- to open tube, remove cap and pierce foil seal with point of cap
- keep tightly closed when not in use
- store at controlled room temperature 68-77°F (20-25°C)

Inactive ingredients

flavor, glycerin, hydroxyethylcellulose

Questions or comments?

call toll free at **1-800-962-2345**

PRINCIPAL DISPLAY PANEL - 122 g Tube Carton - Mint

NDC 0126-0192-93

Colgate®

Gel•Kam®

0.4% Stable Stannous Fluoride

PREVENTATIVE TREATMENT GEL

For Cavity Protection and Sensitive Teeth

MINT

NET WT 4.3 OZ (122 g)

Drug Facts (continued)

Other information

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- this product may produce surface staining of the teeth. Adequate toothbrushing may prevent these stains which are not harmful or permanent and may be removed by your dentist
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- store at controlled room temperature 68-77°F (20-26°C)

Inactive ingredients flavor, glycerin, hydroxyethylcellulose

Questions or comments? call toll free at 1-800-962-2345

Rev. 05/16

Colgate Oral Pharmaceuticals, Inc.,
a subsidiary of Colgate-Palmolive Company
New York, NY 10022 U.S.A.
www.colgateprofessional.com



NDC 0126-0192-93

Colgate[®]
Gel·Kam[®]

0.4% Stable Stannous Fluoride

PREVENTATIVE TREATMENT GEL

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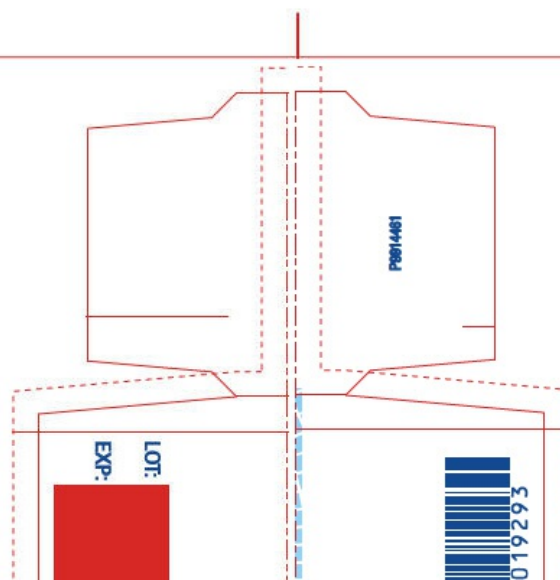
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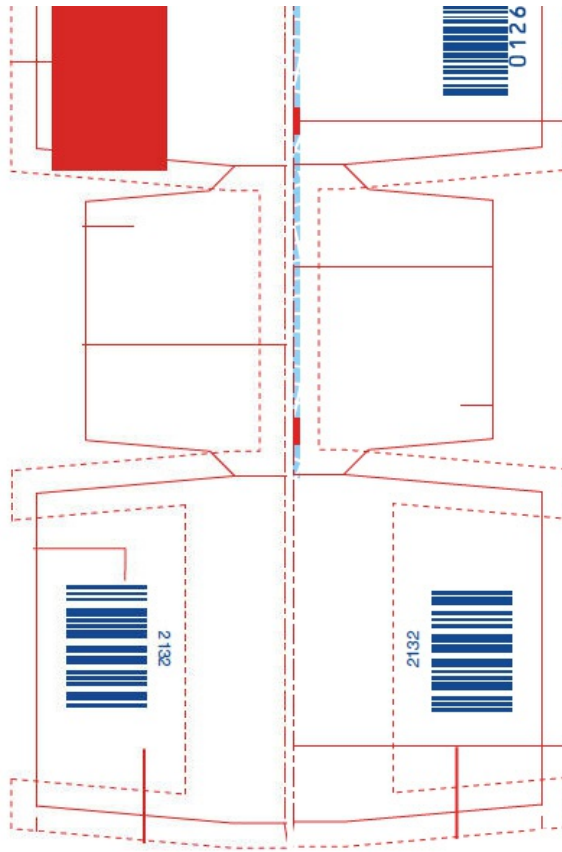
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PRINCIPAL DISPLAY PANEL - 122 g Tube Carton - Fruit and Berry

NDC 0126-0165-93

Colgate®

Gel•Kam®

0.4% Stable Stannous Fluoride
PREVENTATIVE TREATMENT GEL
For Cavity Protection and Sensitive Teeth
FRUIT & BERRY

NET WT 4.3 OZ (122 g)

Drug Facts (continued)

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Inactive ingredients flavor, glycerin, hydroxyethylcellulose

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Rev. 05/16

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www.colgateprofessional.com



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Gel·Kam®

0.4% Stable Stannous Fluoride

PREVENTATIVE TREATMENT GEL

For Cavity Protection and Sensitive Teeth

FRUIT & BERRY

NDC 0126-0165-93



NET WT 4.3 OZ (122 g)

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PREVENTATIVE TREATMENT GEL

For Cavity Protection and Sensitive Teeth

FRUIT & BERRY

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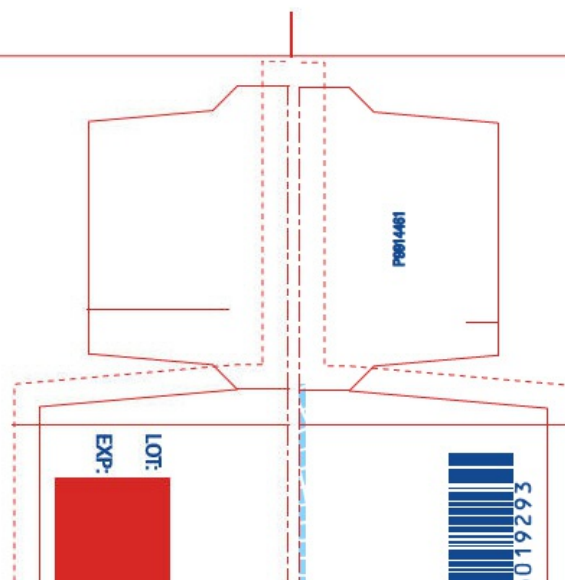
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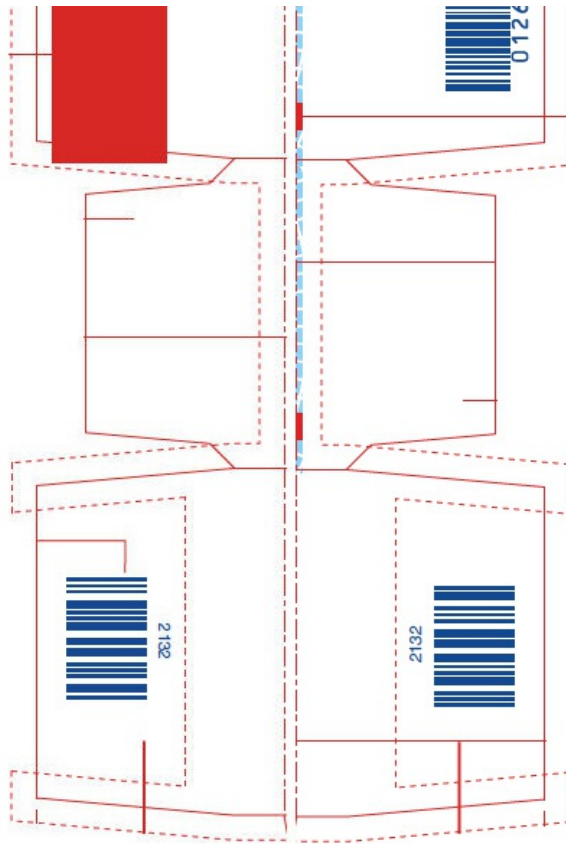
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GEL-KAM MINT

stannous fluoride gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0126-0192
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYETHYL CELLULOSE (2000 MPAS AT 1%) (UNII: S38J6RZN16)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	PEPPERMINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0126-0192-93	1 in 1 CARTON	01/01/1990	
1		122 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	01/01/1990	

GEL-KAM FRUIT AND BERRY

stannous fluoride gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0126-0165
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYETHYL CELLULOSE (2000 MPAS AT 1%) (UNII: S38J6RZN16)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0126-0165-93	1 in 1 CARTON	01/01/1990	
1		122 g in 1 TUBE; Type 0: Not a Combination Product		

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Labeler - Colgate Oral Pharmaceuticals, Inc. (968801118)

Revised: 12/2019

Colgate Oral Pharmaceuticals, Inc.