

GEL 7 NEUTRAL TOPICAL FLUORIDE GEL MINT- fluoride gel gel, dentifrice
GEL 7 NEUTRAL TOPICAL FLUORIDE GEL STRAWBERRY- fluoride gel gel, dentifrice
Germiphene Corporation

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](#).

Gel 7 Topical Fluoride Gel

Recommended Use:

A topical anticaries preparation for professional dental use only.

Gel 7 contains 2.0% sodium fluoride to supply 1.0% fluoride ion in a thixotropic gel base at pH 7.

Medicinal Ingredient:

1.0 % Fluoride ion

Non-medicinal ingredients:

Purified water, glycerin, potassium sorbate, methyl paraben, polysorbate 80, sodium saccharin, methyl salicylate, acrylic polymer, sodium hydroxide, xanthan gum, and flavouring agents.

Directions:

1. Shake well before using. 2. Fill Germiphene brand disposable gel trays to appropriate level. 3. After thorough prophylaxis, air dry teeth and insert trays for four minutes. 4. Remove trays and have patient expectorate excess gel.

Keep out of reach of children.

Warning/Caution:

Do not eat, drink, or rinse for 30 minutes after treatment. Shake bottle vigorously before dispensing. Do not use if tamper-evident foil seal is broken. Do not store in direct sunlight.

Recommended use: A topical anticaries preparation for professional dental use only. GEL 7 contains 2.0% Sodium Fluoride to supply 1.0% fluoride ion in a thixotropic gel base at pH 7.

Medicinal ingredient: 1.0% Fluoride ion.

Non-medicinal ingredients: Purified water, glycerin, potassium sorbate, methyl paraben, polysorbate 80, sodium saccharin, acrylic polymer, sodium hydroxide, xanthan gum, and flavouring agents.

Directions: 1. Shake well before using. 2. Fill Gemiphene brand disposable gel trays to appropriate level. 3. After thorough prophylaxis, air dry teeth and insert trays for four minutes. 4. Remove trays and have patient expectorate excess gel.

Warning/Caution: Do not eat, drink or rinse for 30 minutes after treatment. Keep out of reach of children. Shake bottle vigorously before dispensing. Do not use if tamper-evident foil seal is broken. Do not store in direct sunlight.



Manufactured by | Fabriqué par:
GERMIPHENE CORPORATION
1379 Colborne Street East
Brantford, ON N3T 5M1 CANADA
800.265.9931 | gemiphene.com



Made in Canada
Fabriqué au Canada

NDC 61508-0179
NPN 02042770

GEL 7

Neutral Topical Fluoride Gel
Gel topique neutre au fluorure



Strawberry | Fraise

(15.2 fl oz)
450mL



Usage recommandé: Une préparation topique anticaries réservée à l'usage dentaire seulement. GEL 7 fournit du fluorure de sodium à 2% soit environ 1% d'ion fluorures dans une préparation de gel thixotrope de pH 7.

Ingredient médicamenteux: Ion de fluorure à 1.0%

Ingédients non médicamenteux: L'eau purifiée, glycérine, sorbate de potassium, p-hydroxybenzoate de méthyle, polysorbate 80, saccharinate de sodium, polymère acrylique, hydroxyde de sodium, gomme de xanthane, et aromatisants.

Mode d'emploi: 1. Bien agiter avant l'emploi. 2. Remplir les porte-fluors Gemiphene jusqu'au niveau approprié. 3. Après des soins prophylaxie, sécher les dents à l'air et appliquer les porte-fluors pendant quatre minutes. 4. Enlever les porte-fluors et demander au patient de cracher le surplus de gel.

Mise en garde: Ne pas manger, boire ou rincer la bouche pendant les 30 minutes suivant le traitement. Garder hors de la portée des enfants. Bien agiter avant l'emploi. Ne pas utiliser si le sceau de sécurité est endommagé. Ne pas exposer directement à la lumière du soleil.

R5

450 mL (15.2 fl oz)

Recommended use: A topical anticaries preparation for professional dental use only. GEL 7 contains 2.0% Sodium Fluoride to supply 1.0% fluoride ion in a thixotropic gel base at pH 7.

Medicinal ingredient: 1.0% Fluoride ion.

Non-medicinal ingredients: Purified water, glycerin, potassium sorbate, methyl paraben, polysorbate 80, sodium saccharin, methyl salicylate, acrylic polymer, sodium hydroxide, xanthan gum, and flavouring agents.

Directions: 1. Shake well before using. 2. Fill Germiphene brand disposable gel trays to appropriate level. 3. After thorough prophylaxis, air dry teeth and insert trays for four minutes. 4. Remove trays and have patient expectorate excess gel.

Warning/Caution: Do not eat, drink or rinse for 30 minutes after treatment. Keep out of reach of children. Shake bottle vigorously before dispensing. Do not use if tamper-evident foil seal is broken. Do not store in direct sunlight.



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NDC 61508-0176

NPN 02042770

GEL 7

Neutral Topical Fluoride Gel

Gel topique neutre au fluorure



Mint | Menthe

(15.2 fl oz)

450mL



Usage recommandé: Une préparation topique anticarie réservée à l'usage dentaire seulement. GEL 7 fournit du fluorure de sodium à 2%, soit environ 1% d'ion fluorures dans une préparation de gel thixotrope de pH 7.

Ingédient médicamenteux: Ion de fluorure à 1.0%

Ingédients non médicamenteux: L'eau purifiée, glycérine, sorbate de potassium, p-hydroxybenzoate de méthyle, polysorbate 80, saccharinate de sodium, salicylate de méthyle, polymère acrylique, hydroxyde de sodium, gomme de xanthane, et aromatisants.

Mode d'emploi: 1. Bien agiter avant l'emploi. 2. Remplir les porte-fluors Germiphene jusqu'au niveau approprié. 3. Après des soins prophylaxie, sécher les dents à l'air et appliquer les porte-fluors pendant quatre minutes. 4. Enlever les porte-fluors et demander au patient de cracher le surplus de gel.

Mise en garde: Ne pas manger, boire ou rincer la bouche pendant les 30 minutes suivant le traitement. Garder hors de la portée des enfants. Bien agiter avant l'emploi. Ne pas utiliser si le sceau de sécurité est endommagé. Ne pas exposer directement à la lumière du soleil.

R5

GEL 7 NEUTRAL TOPICAL FLUORIDE GEL MINT

fluoride gel gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61508-0176
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	0.3 g in 100 g
METHYL PARABEN (UNII: A2I8C7HI9T)	0.08 g in 100 g
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	0.1 g in 100 g
GLYCERIN (UNII: PDC6A3C0OX)	7 g in 100 g
SPEARMINT (UNII: J7I2T6IV1N)	1 g in 100 g
METHYL SALICYLATE (UNII: LAV5U5022Y)	0.1 g in 100 g
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	1 g in 100 g

POLYSORBATE 80 (UNII: 6OZP39ZG8H)	0.1 g in 100 g
WATER (UNII: 059QF0KO0R)	86.9 g in 100 g
XANTHAN GUM (UNII: TTV12P4NEE)	1 g in 100 g
SODIUM HYDROXIDE (UNII: 55X04QC32I)	0.425 g in 100 g

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61508-0176-1	450 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/03/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/03/2017	

GEL 7 NEUTRAL TOPICAL FLUORIDE GEL STRAWBERRY

fluoride gel gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61508-0179
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	0.3 g in 100 g
METHYL PARABEN (UNII: A2I8C7HI9T)	0.08 g in 100 g
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	0.1 g in 100 g
GLYCERIN (UNII: PDC6A3C0OX)	7 g in 100 g
STRAWBERRY (UNII: 4J2TY8Y81V)	0.4 g in 100 g
METHYL SALICYLATE (UNII: LAV5U5022Y)	0.1 g in 100 g
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	1 g in 100 g

POLYSORBATE 80 (UNII: 6OZP39ZG8H)	0.1 g in 100 g
WATER (UNII: 059QF0KO0R)	87.5 g in 100 g
XANTHAN GUM (UNII: TTV12P4NEE)	1 g in 100 g
SODIUM HYDROXIDE (UNII: 55X04QC32I)	0.481 g in 100 g

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor	STRAWBERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61508-0179-1	450 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/03/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/03/2017	

Labeler - Germiphene Corporation (206412512)

Revised: 2/2017

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