

60 SECOND GEL BUBBLEGUM- fluoride gel gel, dentifrice
60 SECOND GEL STRAWBERRY- fluoride gel gel, dentifrice
60 SECOND GEL GRAPE- fluoride gel gel, dentifrice
60 SECOND GEL MINT- fluoride gel gel, dentifrice
60 SECOND GEL ORANGE CREAM- 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](#).

60 Second Gel

Recommended use or purpose:

A topical APF anticaries preparation for dental use only.

1.23% fluoride ion from sodium fluoride and hydrofluoric acid. Optimized low pH for a complete fluoride treatment in 60 seconds.

Medicinal Ingredient:

1.23% fluoride ion

Non-medicinal ingredients:

Water, glycerin, sodium saccharin, methyl paraben, potassium sorbate, phosphoric acid, hydrofluoric acid, acrylic polymer, silicon dioxide, zanthan gum, polysorbate 80 & flavoring agents.

Directions:

Shake well before using. Fill Germiphene brand disposable trays to appropriate level. After prophylaxis, air dry teeth and insert trays for one minute. 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. Do not use if tamper-evident seal is broken. Do not store in direct sunlight.

Usage recommandé :

Une préparation anticaries FPA topique à usage dentaire seulement. L'ion de fluorure 1,23 % provient du fluorure de sodium et de l'acide fluorhydrique. Le faible pH optimisé procure un traitement au fluorure complet en 60 secondes.

Ingrédient médicamenteux :
Ion de fluorure 1,23 %

Ingrédients non médicamenteux :
Eau, glycérine, saccharinate de sodium, p-hydroxybenzoate de méthyle, sorbate de potassium, acide phosphorique, acide fluorhydrique, polymère acrylique, dioxyde de silicium, gomme de xanthane, polysorbate et aromatisants.

Mode d'emploi :
Bien agiter avant l'emploi.
Remplir les porte-fluors Germiphene jusqu'au niveau approprié. Après la prophylaxie, asscher les dents et insérer les porte-fluors pendant une minute. Retirer les porte-fluors et demander au patient de cracher l'excès de gel.

Avertissement/mise en garde :
Au terme du traitement, ne pas manger, boire ou rincer avant 30 minutes. Garder hors de la portée des enfants. Ne pas utiliser si le sceau de sécurité est endommagé. Ne pas exposer aux rayons de soleil directs.



Recommended use or purpose:
A topical APF anticaries preparation for dental use only. 1.23% fluoride ion from sodium fluoride and hydrofluoric acid. Optimized low pH for a complete fluoride treatment in 60 seconds.

Medicinal ingredient:
1.23% fluoride ion

Non-medicinal ingredients:
Water, glycerin, sodium saccharin, methyl paraben, potassium sorbate, phosphoric acid, hydrofluoric acid, acrylic polymer, silicon dioxide, xanthan gum, polysorbate 80 & flavoring agents.

Directions:
Shake well before using.
Fill Germiphene brand disposable trays to appropriate level. After prophylaxis, air dry teeth and insert trays for one minute; 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. Do not use if tamper-evident seal is broken. Do not store in direct sunlight.

Manufactured by:
Germiphene Corporation
1379 Colborne St. E, Brantford,
ON N3T 5M1 CANADA
1-800-265-9931
ID CODE: G6-OC

Usage recommandé :

Une préparation anticaries FPA topique à usage dentaire seulement. L'ion de fluorure à 1,23 % provient du fluorure de sodium et de l'acide fluorhydrique. Le faible pH optimisé procure un traitement au fluorure complet en 60 secondes.

Ingrédient médicamenteux :
Ion de fluorure à 1,23 %

Ingrédients non médicamenteux :
Eau, glycérine, saccharinate de sodium, p-hydroxybenzoate de méthyle, sorbate de potassium, acide phosphorique, acide fluorhydrique, polymère acrylique, dioxyde de silicium, gomme de xanthane, polysorbate et aromatisants.

Mode d'emploi :
Bien agiter avant l'emploi.
Remplir les porte-fluors Germiphene jusqu'au niveau approprié. Après la prophylaxie, asscher les dents et insérer les porte-fluors pendant une minute. Retirer les porte-fluors et demander au patient de cracher l'excès de gel.

Avertissement/mise en garde :
Au terme du traitement, ne pas manger, boire ou rincer avant 30 minutes. Garder hors de la portée des enfants. Ne pas utiliser si le sceau de sécurité est endommagé. Ne pas exposer aux rayons de soleil directs.



Recommended use or purpose:
A topical APF anticaries preparation for dental use only. 1.23% fluoride ion from sodium fluoride and hydrofluoric acid. Optimized low pH for a complete fluoride treatment in 60 seconds.

Medicinal ingredient:
1.23% fluoride ion

Non-medicinal ingredients:
Water, glycerin, sodium saccharin, methyl paraben, potassium sorbate, phosphoric acid, hydrofluoric acid, acrylic polymer, silicon dioxide, xanthan gum, polysorbate 80 & flavoring agents.

Directions:
Shake well before using.
Fill Germiphene brand disposable trays to appropriate level. After prophylaxis, air dry teeth and insert trays for one minute; 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. Do not use if tamper-evident seal is broken. Do not store in direct sunlight.

Manufactured by:
Germiphene Corporation
1379 Colborne St. E, Brantford,
ON N3T 5M1 CANADA
1-800-265-9931
ID CODE: G6-SP

Usage recommandé :

Une préparation anticariéuse FPA topique usage dentaire seulement. L'ion de fluorure 1,23 % provient du fluorure de sodium et de l'acide fluorhydrique. Le faible pH optimise procure un traitement au fluorure complet en 60 secondes.

Ingrédients médicamenteux :
Ion de fluorure 1,23 %

Ingrédients non médicamenteux :
Eau, glycérine, saccharinate de sodium, p-hydroxybenzoate de méthyle, sorbate de potassium, acide phosphorique, acide fluorhydrique, polymère acrylique, dioxyde de silicium, gomme de xanthane, polysorbate et aromatisants.

Mode d'emploi :

Bien agiter avant l'emploi.
Remplir les porte-fluors Germiphène jusqu'au niveau approprié. Après la prophylaxie, asscher les dents et insérer les porte-fluors pendant une minute. Retirer les porte-fluors et demander au patient de cracher l'excès de gel.

Avertissement/mise en garde :

Au terme du traitement, ne pas manger, boire ou rincer avant 30 minutes. Garder hors de la portée des enfants. Ne pas utiliser si le sceau de sécurité est endommagé. Ne pas exposer aux rayons de soleil directs.



Recommended use or purpose:

A topical APF anticaries preparation for dental use only. 1.23% fluoride ion from sodium fluoride and hydrofluoric acid. Optimized low pH for a complete fluoride treatment in 60 seconds.

Medicinal ingredient:
1.23% fluoride ion

Non-medicinal ingredients:
Water, glycerin, sodium saccharin, methyl paraben, potassium sorbate, phosphoric acid, hydrofluoric acid, acrylic polymer, silicon dioxide, xanthan gum, polysorbate 80 & flavoring agents.

Directions:

Shake well before using.

Fill Germiphène brand disposable trays to appropriate level. After prophylaxis, air dry teeth and insert trays for one minute; 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. Do not use if tamper-evident seal is broken. Do not store in direct sunlight.

Manufactured by:

Germiphène Corporation
1379 Colborne St. E, Brantford,
ON N3T 5M1 CANADA
1-800-265-9931
ID CODE: G6-GR

Usage recommandé :

Une préparation anticariéuse FPA topique usage dentaire seulement. L'ion de fluorure 1,23 % provient du fluorure de sodium et de l'acide fluorhydrique. Le faible pH optimise procure un traitement au fluorure complet en 60 secondes.

Ingrédients médicamenteux :
Ion de fluorure 1,23 %

Ingrédients non médicamenteux :
Eau, glycérine, saccharinate de sodium, p-hydroxybenzoate de méthyle, sorbate de potassium, acide phosphorique, acide fluorhydrique, polymère acrylique, dioxyde de silicium, gomme de xanthane, polysorbate et aromatisants.

Mode d'emploi :

Bien agiter avant l'emploi.
Remplir les porte-fluors Germiphène jusqu'au niveau approprié. Après la prophylaxie, asscher les dents et insérer les porte-fluors pendant une minute. Retirer les porte-fluors et demander au patient de cracher l'excès de gel.

Avertissement/mise en garde :

Au terme du traitement, ne pas manger, boire ou rincer avant 30 minutes. Garder hors de la portée des enfants. Ne pas utiliser si le sceau de sécurité est endommagé. Ne pas exposer aux rayons de soleil directs.



Recommended use or purpose:

A topical APF anticaries preparation for dental use only. 1.23% fluoride ion from sodium fluoride and hydrofluoric acid. Optimized low pH for a complete fluoride treatment in 60 seconds.

Medicinal ingredient:
1.23% fluoride ion

Non-medicinal ingredients:
Water, glycerin, sodium saccharin, methyl paraben, potassium sorbate, phosphoric acid, hydrofluoric acid, acrylic polymer, silicon dioxide, xanthan gum, polysorbate 80 & flavoring agents.

Directions:

Shake well before using.

Fill Germiphène brand disposable trays to appropriate level. After prophylaxis, air dry teeth and insert trays for one minute; 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. Do not use if tamper-evident seal is broken. Do not store in direct sunlight.

Manufactured by:

Germiphène Corporation
1379 Colborne St. E, Brantford,
ON N3T 5M1 CANADA
1-800-265-9931
ID CODE: G6-BG

Usage recommandé :

Une préparation anticariéuse FPA topique usage dentaire seulement. L'ion de fluorure 1,23 % provient du fluorure de sodium et de l'acide fluorhydrique. Le faible pH optimisé procure un traitement au fluorure complet en 60 secondes.

Ingrédients médicamenteux :

Ion de fluorure 1,23 %

Ingrédients non médicamenteux :

Eau, glycérine, saccharinate de sodium, p-hydroxybenzoate de méthyle, sorbate de potassium, acide phosphorique, acide fluorhydrique, polymère acrylique, dioxyde de silicium, gomme de xanthane, polysorbate et aromatisants.

Mode d'emploi :**Bien agiter avant l'emploi.**

Remplir les porte-fluors Germiphene jusqu'au niveau approprié. Après la prophylaxie, asscher les dents et insérer les porte-fluors pendant une minute. Retirer les porte-fluors et demander au patient de cracher l'excès de gel.

Avertissement/mise en garde :

Au terme du traitement, ne pas manger, boire ou rincer avant 30 minutes. Garder hors de la portée des enfants. Ne pas utiliser si le sceau de sécurité est endommagé. Ne pas exposer aux rayons de soleil directs.

**Recommended use or purpose:**

A topical APF anticaries preparation for dental use only. 1.23% fluoride ion from sodium fluoride and hydrofluoric acid. Optimized low pH for a complete fluoride treatment in 60 seconds.

Medicinal ingredient:

1.23% fluoride ion

Non-medicinal ingredients:

Water, glycerin, sodium saccharin, methyl paraben, potassium sorbate, phosphoric acid, hydrofluoric acid, acrylic polymer, silicon dioxide, xanthan gum, polysorbate 80 & flavoring agents.

Directions:**Shake well before using.**

Fill Germiphene brand disposable trays to appropriate level. After prophylaxis, air dry teeth and insert trays for one minute; 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. Do not use if tamper-evident seal is broken. Do not store in direct sunlight.

Manufactured by:

Germiphene Corporation
1379 Colborne St. E, Brantford,
ON N3T 5M1 CANADA
1-800-265-9931

ID CODE: G6-5

60 SECOND GEL BUBBLEGUM

fluoride gel gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61508-0163
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.69 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	0.55 g in 100 g
METHYL PARABEN (UNII: A2I8C7HI9T)	0.08 g in 100 g
WATER (UNII: 059QF0K00R)	84.365 g in 100 g
PHOSPHORIC ACID (UNII: E4GA8884NN)	0.933 g in 100 g
GLYCERIN (UNII: PDC6A3C0OX)	7 g in 100 g
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	0.1 g in 100 g
HYDROFLUORIC ACID (UNII: RGL5YE86CZ)	1 g in 100 g
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	1 g in 100 g
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	0.2 g in 100 g

XANTHAN GUM (UNII: TTV12P4NEE)	1 g in 100 g
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	0.1 g in 100 g

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61508-0163-1	450 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/24/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/24/2017	

60 SECOND GEL STRAWBERRY

fluoride gel gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61508-0169
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.69 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SILICON DIO XIDE (UNII: ETJ7Z6XBU4)	0.55 g in 100 g
METHYL PARABEN (UNII: A2I8C7HI9T)	0.08 g in 100 g
WATER (UNII: 059QF0KO0R)	85.965 g in 100 g
PHOSPHORIC ACID (UNII: E4GA8884NN)	0.933 g in 100 g
GLYCERIN (UNII: PDC6A3C0OX)	7 g in 100 g
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	0.1 g in 100 g
HYDROFLUORIC ACID (UNII: RGL5YE86CZ)	1 g in 100 g
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	1 g in 100 g
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	0.2 g in 100 g

XANTHAN GUM (UNII: TTV12P4NEE)	1 g in 100 g
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	0.1 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:61508-0169-1	450 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/24/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/24/2017	

60 SECOND GEL GRAPE

fluoride gel gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61508-0165
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.69 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SILICON DIO XIDE (UNII: ETJ7Z6XBU4)	0.55 g in 100 g
METHYL PARABEN (UNII: A2I8C7HI9T)	0.08 g in 100 g
WATER (UNII: 059QF0KO0R)	86.265 g in 100 g
PHOSPHORIC ACID (UNII: E4GA8884NN)	0.933 g in 100 g
GLYCERIN (UNII: PDC6A3C0OX)	7 g in 100 g
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	0.1 g in 100 g
HYDROFLUORIC ACID (UNII: RGL5YE86CZ)	1 g in 100 g
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	1 g in 100 g
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	0.2 g in 100 g

XANTHAN GUM (UNII: TTV12P4NEE)	1 g in 100 g
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	0.1 g in 100 g

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61508-0165-1	450 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/24/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/24/2017	

60 SECOND GEL MINT

fluoride gel gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61508-0166
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.69 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	0.549 g in 100 g
METHYL PARABEN (UNII: A2I8C7HI9T)	0.08 g in 100 g
WATER (UNII: 059QF0KO0R)	85.065 g in 100 g
PHOSPHORIC ACID (UNII: E4GA8884NN)	0.933 g in 100 g
GLYCERIN (UNII: PDC6A3C0OX)	7 g in 100 g
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	0.1 g in 100 g
HYDROFLUORIC ACID (UNII: RGL5YE86CZ)	0.999 g in 100 g
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	0.999 g in 100 g
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	0.2 g in 100 g

XANTHAN GUM (UNII: TTV12P4NEE)	0.999 g in 100 g
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	0.1 g in 100 g
METHYL SALICYLATE (UNII: LAV5U5022Y)	0.3 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:61508-0166-1	450 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/24/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/24/2017	

60 SECOND GEL ORANGE CREAM

fluoride gel gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61508-0167
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.69 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	0.549 g in 100 g
METHYLPARABEN (UNII: A2I8C7HI9T)	0.08 g in 100 g
WATER (UNII: 059QF0KO0R)	847.665 g in 100 g
PHOSPHORIC ACID (UNII: E4GA8884NN)	0.933 g in 100 g
GLYCERIN (UNII: PDC6A3C0OX)	7 g in 100 g
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	0.1 g in 100 g
HYDROFLUORIC ACID (UNII: RGL5YE86CZ)	0.999 g in 100 g
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	0.999 g in 100 g

SACCHARIN SODIUM (UNII: SB8ZUX40TY)	0.2 g in 100 g
XANTHAN GUM (UNII: TTV12P4NEE)	0.999 g in 100 g
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	0.1 g in 100 g

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor	ORANGE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61508-0167-1	450 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/24/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/24/2017	

Labeler - Germiphene Corporation (206412512)

Revised: 2/2017

Germiphene Corporation