

**FLOAM TOPICAL FLOAM FLUORIDE- sodium fluoride aerosol, foam**  
**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](#).*

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**Recommended use:**

A topical anticaries preparation for professional dental use only.

1.23% fluoride ion (from 1.69% sodium fluoride and 0.5% hydrogen fluoride) in a flavored base at pH 4.

**Medicinal ingredients:**

1.23% fluoride ion.

**Non-medicinal ingredients:**

Water, glycerin, cocamidopropyl betaine, xylitol, phosphoric acid, flavouring agents, xanthan gum, polysorbate 20, poloxamer 407, sodium saccharin, PVP, sodium benzoate

**Directions:**

1. Use after thorough prophylaxis. 2. Shake prior to dispensing. 3. Place nozzle tip to applicator floor and press down on trigger to dispense foam. NOTE: Foam will expand to fill tray. 4. Immediately place trays in mouth and have patient bite down lightly for one minute. 5. Remove trays and have patient expectorate excess.

**Warning:**

Do not eat, drink, or rinse for 30 minutes after treatment. Do not puncture or incinerate container or store at temperatures over 50°C. Do not use in presence of open flame or spark. Contents under pressure; do not place in hot water or near any sources of heat.

Keep out of reach of children.

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Manufactured by / Fabriqué par  
Gemiphene Corporation  
1379 Colborne St. E. Brantford, ON N3T 5M1  
CANADA | (800) 265.9931 | www.gemiphene.com

Correct Dispensing Position  
Position correcte

Incorrect Dispensing Position  
Position incorrecte

**Floam**  
NPN 02198703

**Topical foam fluoride**  
**Fluorure topique en mousse**

Mintnight  
Menthe

withavec  
Xylitol

4 oz  
(125g)

- Alcohol free | Sans alcool
- Dye free | Sans colorant
- Gluten free | Sans gluten

**Usage recommandé:** Une préparation topique contre la carie pour usage professionnel seulement. 1.23% de ions fluorure de sodium et fluorure d'hydrogène dans une base de saveur contenant un pH de 4.

**Ingédient médicamenteux:**  
Ion de fluorure à 1,23%

**Ingédient non médicamenteux:** Eau, glycérine, bétaine de cocamidopropyle, xylitol, acide phosphorique, aromatisants, gomme Xanthan, polysorbate 20, poloxamère 407, saccharinate de sodium, PVP, benzoate de sodium.

**Mode D'emploi:** 1. Utilisez après un prophylaxie rigoureuse. 2. Secouer avant la distribution. 3. Placez l'embout de l'applicateur sur la base du porte-fluor et pressez sur la détente pour obtenir la mousse. À NOTER que la mousse s'étendra pour remplir le porte-fluor. 4. Placez le porte-fluor immédiatement dans la bouche de la patiente ou du patient et demandez-lui de mordre légèrement pendant une minute. 5. Enlevez les porte-fluors et demandez à la patiente ou au patient de recracher l'excès de mousse.

**Mise en garde:** Ne pas manger ni boire pendant 30 minutes. Garder hors de la portée des enfants. Ne pas percer le contenant, ni le jeter au feu, ni le conserver à des températures dépassant 50°C. Ne pas utiliser en présence de la flamme nue ou d'étincelles. Contenu sous pression. Ne pas mettre dans l'eau chaude, ni près de radiateurs, poêles ou autres sources de chaleur.

## FLOAM TOPICAL FLOAM FLUORIDE

sodium fluoride aerosol, foam

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61508-1120
<b>Route of Administration</b>	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.732 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
HYDROFLUORIC ACID (UNII: RGL5YE86CZ)	1.039 g in 100 g
GLYCERIN (UNII: PDC6A3C0OX)	14.96 g in 100 g
POLYSORBATE 20 (UNII: 7T1F30V5YH)	0.609 g in 100 g
XANTHAN GUM (UNII: TTV12P4NEE)	0.798 g in 100 g
POLOXAMER 407 (UNII: TUF2IVW3M2)	2.991 g in 100 g
SODIUM BENZOATE (UNII: OJ245FE5EU)	0.1 g in 100 g

<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	0.199 g in 100 g
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	3.99 g in 100 g
<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3011KX)	4.985 g in 100 g
<b>POVIDONE</b> (UNII: FZ989GH94E)	0.1 g in 100 g
<b>SODIUM PHOSPHATE, DIBASIC</b> (UNII: GR686LBA74)	2.493 g in 100 g
<b>WATER</b> (UNII: 059QF0KO0R)	66.004 g in 100 g

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BERRY, MINT, ORANGE, STRAWBERRY, BUBBLE GUM, GRAPE	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61508-1120-1	125 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/06/2017	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/06/2017	

**Labeler** - Germiphene Corporation (206412512)

### Establishment

Name	Address	ID/FEI	Business Operations
Germiphene Corporation		206412512	manufacture(61508-1120)