

NEUTRAGEL- sodium fluoride 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](#).

Neutragel

Recommended use:

A topical anticaries preparation for dental use only.

1.1% Neutral sodium fluoride gel for topical fluoride gel treatments. Neutragel provides 0.5% fluoride ion from sodium fluoride in a neutral (pH7), unflavored, unsweetened, stabilized gel base. The special formulation is non-etching on porcelain or ceramic filled restorations. Ideal for chemotherapy and Zerostomia patients.

Medicinal ingredient:

0.5% fluoride ion (from 1.1% sodium fluoride)

Non-medicinal ingredients:

Purified water, glycerin carboxymethylcellulose sodium, sodium benzoate, sodium citrate, and citric acid anhydrous.

Directions:

1. Fill Germiphene brand disposable Gel Trays. After thorough prophylaxis, air dry teeth and insert trays for four minutes. 2. Remove trays and excess gel.

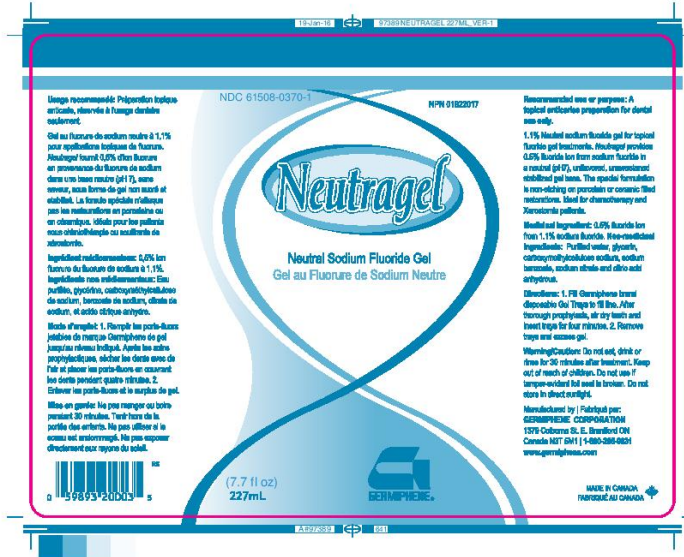
Warning/Caution:

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

Keep out of reach of children.

UPC CODE IS BELOW MINIMUM SIZE

3.750"

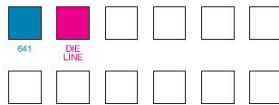


5.000"

← PRESS DIRECTION →

PROOF

Label Design Ltd
 Job Number: 97389
 Purchase Order: PLT 9261
 Job: 97389 NEUTRAGEL 227ML
 Date: JAN-19-2016
 Revision Date:
 Previous Job Number:
 File: NEUTRAGEL 227ML_VER-1



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 SIGNATURE & DATE

Usage recommandé: Préparation topique anticarie, réservée à l'usage dentaire seulement.

Gel au fluorure de sodium neutre à 1,1% pour applications topiques de fluorure. *Neutrage!* fournit 0,5% d'ion fluorure en provenance du fluorure de sodium dans une base neutre (pH 7), sans saveur, sous forme de gel non sucré et stabilisé. La formule spéciale n'attaque pas les restaurations en porcelaine ou en céramique. Idéale pour les patients sous chimiothérapie ou souffrants de xérostomie.

Ingrédient médicamenteux: 0,5% ion fluorure du fluorure de sodium à 1,1% **Ingrédients non médicamenteux:** Eau purifiée, glycérine, carboxyméthylcellulose de sodium, benzoate de sodium, citrate de sodium, et acide citrique anhydre.

Mode d'emploi: 1. Remplir les porte-fleurs jetables de marque Germiphene de gel jusqu'au niveau indiqué. Après les soins prophylactiques, sécher les dents avec de l'air et placer les porte-fleurs en couvrant les dents pendant quatre minutes. 2. Enlever les porte-fleurs et le surplus de gel.

Mise en garde: Ne pas manger ou boire pendant 30 minutes. Tenir hors de la portée des enfants. Ne pas utiliser si le sceau est endommagé. Ne pas exposer directement aux rayons du soleil.



NDC 61508-0370-2

NPN 01922017

Neutrage!

Neutral Sodium Fluoride Gel
Gel au Fluorure de Sodium Neutre



(15.2 fl oz)
450mL

Recommended use or purpose: A topical anticaries preparation for dental use only.

1.1% Neutral sodium fluoride gel for topical fluoride gel treatments. *Neutrage!* provides 0.5% fluoride ion from sodium fluoride in a neutral (pH7), unflavored, unsweetened stabilized gel base. The special formulation is non-etching on porcelain or ceramic filled restorations. Ideal for chemotherapy and Xerostomia patients.

Medicinal ingredient: 0.5% fluoride ion from 1.1% sodium fluoride. **Non-medicinal ingredients:** Purified water, glycerin, carboxymethylcellulose sodium, sodium benzoate, sodium citrate and citric acid anhydrous.

Directions: 1. Fill Germiphene brand disposable Gel Trays to fill line. After thorough prophylaxis, air dry teeth and insert trays for four minutes. 2. Remove trays and 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 foil seal is broken. Do not store in direct sunlight.

Manufactured by | Fabriqué par:
GERMIPHENE CORPORATION
1379 Colborne St. E. Brantford ON
Canada N3T 5M1 | 1-800-265-9931
www.germiphene.com

MADE IN CANADA
FABRIQUÉ AU CANADA

NEUTRAGEL

sodium fluoride gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61508-0370
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	2.6 g in 100 g

WATER (UNII: 059QF0KO0R)	86.1 g in 100 g
GLYCERIN (UNII: PDC6A3C0OX)	10 g in 100 g
SODIUM BENZOATE (UNII: OJ245FE5EU)	0.12 g in 100 g
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	0.007 g in 100 g
SODIUM CITRATE (UNII: 1Q73Q2JULR)	0.093 g in 100 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61508-0370-1	120 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/06/2017	
2	NDC:61508-0370-2	450 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(61508-0370)

Revised: 2/2017

Germiphene Corporation