

NEUTRARINSE 2% NEUTRAL SODIUM FLORIDE ORAL RINSE WHITE GRAPE- sodium fluoride rinse

NEUTRARINSE 2% NEUTRAL SODIUM FLORIDE ORAL RINSE RASPBERRY SPLASH- sodium fluoride rinse

NEUTRARINSE 2% NEUTRAL SODIUM FLORIDE ORAL RINSE REFRESHMINT- sodium fluoride rinse

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](#).

Neutrarinse

Recommended use:

For topical application to aid in the prevention of dental caries.

Neutral pH makes Neutrarinse especially safe for crowns and restorations.

Medicinal ingredient:

2.0% Neutral sodium fluoride

Non-medicinal ingredients:

Water, sodium phosphate dibasic, parabens, sorbitol, xylitol, sodium saccharin, ethanol, povidone, and flavouring agents.

Directions:

Dispense up to 10 mL of Neutrarinse 2% Neutral Sodium Fluoride Solution into a measuring cup. Instruct patient to rinse vigorously for one minute with up to 10 mL of the solution around and between teeth, then expectorate. **DO NOT SWALLOW.** Instruct patient not to eat, drink, or rinse mouth for at least 30 minutes.

Neutrarinse 2% Neutral Sodium Fluoride Solution may also be applied full strength with cotton pledgets, to teeth isolated with cotton rolls.

Warning:

The product is intended for topical use only, not for internal use. Not recommended for use by children under 6 years of age.

Instruct patient not to eat, drink, or rinse mouth for at least 30 minutes. Do not use if tamper-evident seal is broken. Do not store in direct sunlight.

Keep out of reach of children.

Usage recommandé: Pour application topique dans la prévention contre la carie dentaire. Le pH neutre est particulièrement sans danger et sécuritaire pour les couronnes et les restaurations.

Ingredient médicamenteux: Fluorure de sodium neutre 2,0%

Ingédients non médicamenteux: Eau, phosphate dibasique de sodium, p-hydroxybenzoate, sorbitol, xylitol, saccharine de sodium, éthanol, povidone, et aromatisants.

Mode d'emploi: Verser jusqu'à 10 mL de solution au fluorure de sodium neutre 2% Neutrarinse dans un gobelet. Demander au patient de rincer vigoureusement la solution dans la bouche pendant une minute puis cracher. **Ne pas avaler.** Demander au patient de ne pas manger, boire ou rincer la bouche pendant au moins 30 minutes.

La solution au fluorure de sodium neutre 2% Neutrarinse peut également être appliquée non diluée à l'aide de tampons d'ouate sur des dents isolées avec des rouleaux de coton.

Avertissement: Ce produit est conçu pour un usage topique seulement et non pour un usage interne. Non recommandé pour les enfants de moins de 6 ans.

Mise en garde: Demander au patient de ne pas manger, boire ou rincer la bouche pendant au moins 30 minutes, garder hors de la portée des enfants. Ne pas utiliser si le sceau est endommagé. Ne pas exposer aux rayons de soleil directs.

FABRIQUÉ AU CANADA

NDC 61508-0527-1

(67.6 fl oz)

Recommended use or purpose: For topical application to aid in the prevention of dental caries. Neutral pH makes Neutrarinse especially safe for crowns and restorations.

Medicinal ingredient: 2.0% Neutral Sodium Fluoride.

Non-medical ingredients: Water, sodium phosphate dibasic, parabens, sorbitol, xylitol, sodium saccharin, ethanol, povidone, and flavoring agents.

Directions: Dispense up to 10mL of Neutrarinse 2% Neutral Sodium Fluoride Solution into a measuring cup. Instruct patient to rinse vigorously for one minute with up to 10mL of the solution around and between teeth, then expectorate. **DO NOT SWALLOW.** Instruct patient not to eat, drink or rinse mouth for at least 30 minutes.

Neutrarinse 2% Neutral Sodium Fluoride Solution may also be applied full strength with cotton pledgets, to teeth isolated with cotton rolls.

Warning: The product is intended for topical use only, not for internal use. Not recommended for use by children under 6 years of age.

Caution: Instruct patient not to eat, drink or rinse mouth for at least 30 minutes, 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 Street East, Brantford, ON N3T 5M1 1-800-265-9931

MADE IN CANADA

R4

Usage recommandé: Pour application topique dans la prévention contre la carie dentaire. Le pH neutre est particulièrement sans danger et sécuritaire pour les couronnes et les restaurations.

Ingredient médicamenteux: Fluorure de sodium neutre 2,0%

Ingédients non médicamenteux: Eau, phosphate dibasique de sodium, p-hydroxybenzoate, sorbitol, xylitol, saccharine de sodium, éthanol, povidone, et aromatisants.

Mode d'emploi: Verser jusqu'à 10 mL de solution au fluorure de sodium neutre 2% Neutrarinse dans un gobelet. Demander au patient de rincer vigoureusement la solution dans la bouche pendant une minute puis cracher. **Ne pas avaler.** Demander au patient de ne pas manger, boire ou rincer la bouche pendant au moins 30 minutes.

La solution au fluorure de sodium neutre 2% Neutrarinse peut également être appliquée non diluée à l'aide de tampons d'ouate sur des dents isolées avec des rouleaux de coton.

Avertissement: Ce produit est conçu pour un usage topique seulement et non pour un usage interne. Non recommandé pour les enfants de moins de 6 ans.

Mise en garde: Demander au patient de ne pas manger, boire ou rincer la bouche pendant au moins 30 minutes, garder hors de la portée des enfants. Ne pas utiliser si le sceau est endommagé. Ne pas exposer aux rayons de soleil directs.

FABRIQUÉ AU CANADA

NDC 61508-0526-1

(67.6 fl oz)

Recommended use or purpose: For topical application to aid in the prevention of dental caries. Neutral pH makes Neutrarinse especially safe for crowns and restorations.

Medicinal ingredient: 2.0% Neutral Sodium Fluoride.

Non-medical ingredients: Water, sodium phosphate dibasic, parabens, sorbitol, xylitol, sodium saccharin, ethanol, povidone, and flavoring agents.

Directions: Dispense up to 10mL of Neutrarinse 2% Neutral Sodium Fluoride Solution into a measuring cup. Instruct patient to rinse vigorously for one minute with up to 10mL of the solution around and between teeth, then expectorate. **DO NOT SWALLOW.** Instruct patient not to eat, drink or rinse mouth for at least 30 minutes.

Neutrarinse 2% Neutral Sodium Fluoride Solution may also be applied full strength with cotton pledgets, to teeth isolated with cotton rolls.

Warning: The product is intended for topical use only, not for internal use. Not recommended for use by children under 6 years of age.

Caution: Instruct patient not to eat, drink or rinse mouth for at least 30 minutes, 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 Street East, Brantford, ON N3T 5M1 1-800-265-9931

MADE IN CANADA

R5

Usage recommandé: Pour application topique dans la prévention contre la carie dentaire. Le pH neutre est particulièrement sans danger et sécuritaire pour les couronnes et les restaurations.

Ingredient médicamenteux: Fluorure de sodium neutre 2,0%

Ingédients non médicamenteux: Eau, phosphate dibasique de sodium, p-hydroxybenzoate, sorbitol, xylitol, saccharine de sodium, éthanol, povidone, et aromatisants.

Mode d'emploi: Verser jusqu'à 10 mL de solution au fluorure de sodium neutre 2% Neutrarinse dans un gobelet. Demander au patient de rincer vigoureusement la solution dans la bouche pendant une minute puis cracher. **Ne pas avaler.** Demander au patient de ne pas manger, boire ou rincer la bouche pendant au moins 30 minutes.

La solution au fluorure de sodium neutre 2% Neutrarinse peut également être appliquée non diluée à l'aide de tampons d'ouate sur des dents isolées avec des rouleaux de coton.

Avertissement: Ce produit est conçu pour un usage topique seulement et non pour un usage interne. Non recommandé pour les enfants de moins de 6 ans.

Mise en garde: Demander au patient de ne pas manger, boire ou rincer la bouche pendant au moins 30 minutes, garder hors de la portée des enfants. Ne pas utiliser si le sceau est endommagé. Ne pas exposer aux rayons de soleil directs.

FABRIQUÉ AU CANADA

NDC 61508-0528-1

(67.6 fl oz)

Recommended use or purpose: For topical application to aid in the prevention of dental caries. Neutral pH makes Neutrarinse especially safe for crowns and restorations.

Medicinal ingredient: 2.0% Neutral Sodium Fluoride.

Non-medical ingredients: Water, sodium phosphate dibasic, parabens, sorbitol, xylitol, sodium saccharin, ethanol, povidone, and flavoring agents.

Directions: Dispense up to 10mL of Neutrarinse 2% Neutral Sodium Fluoride Solution into a measuring cup. Instruct patient to rinse vigorously for one minute with up to 10mL of the solution around and between teeth, then expectorate. **DO NOT SWALLOW.** Instruct patient not to eat, drink or rinse mouth for at least 30 minutes.

Neutrarinse 2% Neutral Sodium Fluoride Solution may also be applied full strength with cotton pledgets, to teeth isolated with cotton rolls.

Warning: The product is intended for topical use only, not for internal use. Not recommended for use by children under 6 years of age.

Caution: Instruct patient not to eat, drink or rinse mouth for at least 30 minutes, 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 Street East, Brantford, ON N3T 5M1 1-800-265-9931

MADE IN CANADA

R4

NEUTRARINSE 2% NEUTRAL SODIUM FLORIDE ORAL RINSE WHITE GRAPE

sodium fluoride rinse

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61508-0527
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
ALCOHOL (UNII: 3K9958V90M)	1 g in 100 g
METHYL PARABEN (UNII: A2I8C7HI9T)	0.052 g in 100 g
POVIDONE (UNII: FZ989GH94E)	0.3 g in 100 g
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	0.043 g in 100 g
SORBITOL (UNII: 506T60A25R)	15 g in 100 g
WATER (UNII: 059QF0KO0R)	76.4 g in 100 g
XYLITOL (UNII: VCQ006KQ1E)	5 g in 100 g
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	0.01 g in 100 g
PROPYL PARABEN (UNII: Z8IX2SC1OH)	0.01 g in 100 g

Product Characteristics

Color		Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61508-0527-1	2000 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	

NEUTRARINSE 2% NEUTRAL SODIUM FLORIDE ORAL RINSE RASPBERRY SPLASH

sodium fluoride rinse

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61508-0528
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
ALCOHOL (UNII: 3K9958V90M)	1 g in 100 g
METHYLPARABEN (UNII: A2I8C7HI9T)	0.052 g in 100 g
POVIDONE (UNII: FZ989GH94E)	0.3 g in 100 g
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	0.043 g in 100 g
SORBITOL (UNII: 506T60A25R)	15 g in 100 g
WATER (UNII: 059QF0K00R)	76.4 g in 100 g
XYLITOL (UNII: VCQ006KQ1E)	5 g in 100 g
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	0.01 g in 100 g
PROPYLPARABEN (UNII: Z8IX2SC1OH)	0.01 g in 100 g

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61508-0528-1	2000 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	

NEUTRARINSE 2% NEUTRAL SODIUM FLORIDE ORAL RINSE REFRESHMINT

sodium fluoride rinse

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61508-0526
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

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

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	1 g in 100 g
METHYL PARABEN (UNII: A2I8C7HI9T)	0.052 g in 100 g
POVIDONE (UNII: FZ989GH94E)	0.3 g in 100 g
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	0.043 g in 100 g
SORBITOL (UNII: 506T60A25R)	15 g in 100 g
WATER (UNII: 059QF0KO0R)	76.4 g in 100 g
XYLITOL (UNII: VCQ006KQ1E)	5 g in 100 g
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	0.01 g in 100 g
PROPYL PARABEN (UNII: Z8IX2SC1OH)	0.01 g in 100 g

Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61508-0526-1	2000 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(61508-0526, 61508-0527, 61508-0528)