

ACCLEAN DUAL FLUORIDE RINSE 1.24% APF BUBBLEGUM- fluoride liquid
Henry Schein

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.

104-9035 Bubble Gum
Henry Schein Acclean Dual Fluoride Rinse Part B
1.24% APF

Description

A water soluble topical fluoride rinse to assist in preventing dental caries. For professional use only.

Direction

Directions:

Read directions carefully before using. The following treatment method provides a high initial protection level on tooth surfaces.

Adults and children 6 years of age and older: use as indicated below, in conjunction with oral hygiene program.

1. For combined Stannous fluoride and A.P.F treatment, dispense 7 mL of Acclean Stannous fluoride concentrate (part A) and 7 mL of Acclean A.P.F. (part B) into a cup by depressing each plunger once.
2. Add 21 mL of water and mix well. This provides a 0.33% Stannous solution with 0.25% acidulated phosphate fluoride.
3. Instruct patient to rinse mouth with 1/2 of the solution for 60 seconds.
4. Expectorate and repeat the procedure with the remaining solution.
5. Use only freshly prepared solution for each patient.
6. Instruct patient not to eat or drink for 30 minutes after use.

Warning

Children under 12 years of age should be supervised during treatment.

Consult a dentist or doctor before using on children under 6 years of age.

Keep out of reach of children under age 6.

Do not swallow.

Rx Only

Storage

Warnings: Store at room temperature. Do not expose to excessive heat over 40°C, 104°F.

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Made in USA

Rev.02

Main Panel

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135 DURYEA ROAD
MELVILLE, NY 11747 USA

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Hecho en los EEUU/Fabrique aux États-Unis

Un enjuague de fluoruro tóxico soluble en agua para ayudar a prevenir las caries dentales. Para uso profesional solamente.

Indicaciones: Leer las indicaciones atentamente antes de utilizar el producto. El siguiente método de tratamiento proporciona un nivel inicial de alta protección en las superficies dentales. Adultos y niños de 6 años y mayores: utilizar como se indica abajo, manteniendo la costumbre habitual de higiene bucal. Para combinar un tratamiento de fluoruro estannoso y APF: verter 7 mL de concentrado de fluoruro estannoso Acclean (parte A) y 7 mL de A.P.F. Acclean (parte B) en un recipiente oprimiendo, un vez, cada surtidor. Agregar 21 mL de agua y mezclar bien. Esto proporciona una solución de estano de 0.33% con fluoruro de fosfato acidulado de 0.25%. Indicar al paciente de enjuagarse la boca con la mitad de la solución por 60 segundos. Expectorar y repetir el proceso con el resto de la solución. Para cada paciente utilizar, solamente, una solución preparada recientemente. Indicarle al paciente de no comer or tomar durante 30 minutos después del tratamiento. Niños menores de 12 años deben ser supervisados durante el tratamiento. Consultar un dentista o un médico antes de tratar niños menores de 6 años.

Advertencia: Guardar a la temperatura del ambiente. No exponerse al calor excesivo más alto de 40 grados C, 104 grados F. Mantener fuera del alcance de niños menores de 6 años. No lo trague. Bajo prescripción solamente.

Une préparation stable à base d'eau, pour une application topique de fluorure qui contribue à prévenir la formation de caries dentaires. Pour usage professionnel seulement. Mode d'emploi: Veuillez lire attentivement le mode d'emploi avant toute utilisation. La méthode de traitement suivante fournit un haut niveau de protection initiale des surfaces dentales. Adultes et enfants de 6 ans et plus: utiliser tel qu'indiqué ci-dessous, tout en maintenant les habitudes de brossage normales. Pour combiner le traitement au stannofluorure (partie A) et au F.P.A. (partie B), verser 7 mL de concentré au stannofluorure et 7 mL de F.P.A. and un gobelet, en appuyant une fois sur le piston de chaque pompe. Ajouter 21 mL d'eau et bien mélanger. Une solution de stannofluorure à 0,33%, avec du fluorure de phosphate acidulé à 0,25% est ainsi obtenue. Demander au patient de se rincer la bouche avec la moitié de la solution pendant une minute. Faire cracher et répéter l'opération avec le reste de la solution. Demander au patient d'éviter de boire ou de manger dans les 30 minutes qui suivent. Pour chaque client, n'utiliser qu'une solution fraîchement préparée. Les enfants de moins de 12 ans devraient être supervisés lors de l'utilisation de ce produit. Consulter un dentiste ou un médecin avant d'employer ce produit chez des enfants de moins de 6 ans.

Mise en Garde : Entreposer à la température de la pièce. Ne pas exposer à la température excessive excédant 40°C, 104°F. Garder hors de la portée des enfants moins de 6 ans. Ne pas avaler.

Sous prescription seulement

HENRY SCI



NDC

ACCLEAN DUAL FLUORIDE RINSE 1.24% APF BUBBLEGUM

fluoride liquid

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0404-9035
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.02522 g in 1 mL

Product Characteristics

Color	pink	Score	
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0404-9035-03	3 in 1 CASE	03/03/2017	
1	NDC:0404-9035-01	1890 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

Marketing Information

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

Labeler - Henry Schein (012430880)

Revised: 12/2018

Henry Schein