

ACCLEAN 60 SECOND FLUORIDE TREATMENT- fluoride gel

Henry Schein Inc.

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](#).

104-6308 Bubble Gum

Henry Schein Acclean 60 Second Fluoride Treatment Gel

1.23% APF

Description

Henry Schein 104-6308 Bubble Gum Gel

Acclean 60 Second Fluoride Treatment

1.23% APF

16.2 fl oz (480 mL)

NDC 0404-3963-01

A topical anticaries preparation for professional use only.

1.23% fluoride ion from sodium fluoride. Optimized low pH for penetration. Ideal thixotropic action. Artificially flavored.

Directions

Directions:

1. Shake well before using
2. Use after thorough prophylaxis
3. To dispense, fill tray(s) 1/3 with gel
4. Dry teeth completely. Insert tray(s) in mouth and have patient bite down lightly for 60 seconds or up to four minutes for optimal uptake
5. Advise patient not to eat, drink or rinse for 30 minutes after the treatment

Warning

Cautions: Keep out of reach of children.

RX only

Non-Medicinal

Non-Medicinal ingredients: Carboxy methyl cellulose sodium, phosphoric acid, water, red dye, saccharin sodium, titanium dioxide, bubble gum flavor.

Storage

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

Distributed by (in US only): Henry Schein Inc., 135 Duryea Road, Melville, NY 11747 USA

Made in USA

 HENRY SCHEIN®

REF 104-6308

ACCLEAN®

60 Second
Fluoride Treatment

Tratamiento de Fluoruro
en 60 Segundos 1.23% APF


Traitement au fluorure en
60 secondes 1.23% APF

Bubble Gum / Goma de Mascar
Gomme Balloune





NDC: 0404-3963-01



16.2 fl oz (480 mL)

Una Preparación tópica anti-caries para uso profesional solamente.

Ion de Fluoruro al 1.23% derivado de fluoruro de sodio. Su bajo pH permite mejor penetración. Acción tixotrópica ideal. Sabor artificial.

Indicaciones:

1. Agitar bien antes de utilizarlo.
2. Usar después de un tratamiento profiláctico a fondo.
3. Para utilizar, agregar 1/3 de gel en una bandeja.
4. Secar los dientes completamente. Colocar la bandeja(s) en la boca y pedir al paciente de morder suavemente durante 60 segundos o hasta cuatro minutos para una absorción óptima.
5. Informar al paciente de no comer, beber o enjuagarse por 30 minutos después del tratamiento.

Advertencia: Guardar a la temperatura del ambiente. No exponer al calor excesivo más elevado de 40 grados C. Guardar fuera del alcance de los niños.

Recepción sin prescripción solamente

Sous prescription seulement

Préparation topique anti-carie, pour l'usage professionnel seulement.

1,23% d'ions de fluorure dérivés du fluorure de sodium. Un pH faible assure une meilleure pénétration. Parfaite action thixotropique. Saveur artificielle.

Mode d'emploi:

1. Utiliser après traitement prophylactique complet.
2. Avant d'utiliser, remplir le(s) moule(s) au 1/3 avec le gel.
3. Insérer le(s) moule(s) dans la bouche et demander au patient de tenir les dents légèrement serrées pendant 60 secondes.
4. Retirer le(s) moule(s) et demander au patient de cracher tout surplus.
5. Recommander au patient d'éviter de manger, de boire et de se rincer la bouche pendant les 30 minutes suivant le traitement.

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.

Sous prescription seulement

A topical anticaries preparation for professional use only.

1.23% fluoride ion from sodium fluoride. Optimized low pH for penetration. Ideal thixotropic action. Artificially flavored.

Directions:

1. Shake well before using.
2. Use after thorough prophylaxis.
3. To dispense, fill tray(s) 1/3 full with gel.
4. Dry teeth completely. Insert tray(s) in mouth and have patient bite down lightly for 60 seconds or up to four minutes for optimal uptake.
5. Advise patient not to eat, drink or rinse for 30 minutes after the treatment.

Caution: Store at room temperature.

Do not expose to excessive heat over 40°C, 104°F.

Keep out of reach of children.

Rx Only

Distributed by (in US only):

Henry Schein Inc.

135 DURYEA ROAD

MELVILLE, NY 11747 USA

Made in USA

Hecho en los EEUU/Fabriqu  aux  tats-Unis

Rev Date: 2018/01

Rev.03

117878

ACCLEAN 60 SECOND FLUORIDE TREATMENT

fluoride gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0404-3963
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.0272 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:0404-3963-03	12 in 1 CASE	03/03/2017	
1	NDC:0404-3963-01	480 mL in 1 BOTTLE, PLASTIC; 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 Inc. (012430880)

Revised: 12/2018

Henry Schein Inc.