

**CURODONT REPAIR FLUORIDE PLUS- sodium fluoride sponge
CREDENTIS AG**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

CURODONT REPAIR FLUORIDE PLUS - DISTRIBUTED BY STRAUMANN

ACTIVE INGREDIENTS

SODIUM FLUORIDE 0.05% (0.02% W/V FLUORIDE ION)

PURPOSE

ANTICAVITY

USES

AIDS IN THE PREVENTION OF DENTAL CAVITIES

- ANTICAVITY DENTAL RINSE
- RESTORES ENAMEL
- FOR THE TREATMENT OF WHITE SPOTS

WARNING

FOR TOPICAL INTRAORAL USE ONLY. FOR PROFESSIONAL OFFICE USE ONLY. THIS PRODUCT IS NOT INTENDED FOR HOME OR UNSUPERVISED CONSUMER USE.

KEEP OUT OF REACH OF CHILDREN.

DIRECTIONS

Usual dosage is one treatment per tooth. After prophylaxis treatment, remove the pellicle of the concerned tooth by using 2% sodium hypochlorite for 10 seconds. rinse the tooth surface with water. Remove inorganic deposits by pushing together the two cylinders and apply product with sponge on treatment area.

After treatment time of five minutes have patient expectorate residues. For maximum benefits for the prevention of caries, instruct patient not to rinse, eat or drink for 30 minutes. For patients with rampant or active caries, repeat treatment once or twice every six months.

OTHER INFORMATION

DO NOT USE IF SAFETY PACHAGING IS BROKEN OR MISSING.

SINGLE USE ONLY.

STORE IN A DRY AND COOL PLACE.

INACTIVE INGREDIENTS

WATER, CHLORHEXIDINE DIGLUCONATE, TROMETHAMINE, TREHALOSE DIHYDRATE, OLIGOPEPTIDE-104, HYDROXYPROPYL METHYLCELLULOSE

CURODONT™ PLUS REPAIR FLUORIDE

CUROLOX®

DISTRIBUTED BY STRAUMANN

Anticavity dental treatment rinse.
Contains 10 single packed single use applicator with 0.1 ml rinse each.

<p>Drug Facts Continued</p> <p>Directions Usual dosage is one treatment per tooth. After prophylaxis treatment, remove the pellicle of the concerned tooth by using 2% sodium hypochlorite for 20 seconds. Rinse the tooth surface with water. Remove inorganic deposits by using 35% phosphoric acid for 20 seconds. Rinse the tooth surface with water & dry the tooth surface. Activate product by pushing together the two cylinders and apply product with sponge on treatment area.</p> <p>After treatment time of five minutes have patient expectorate residues. For maximum benefits for the prevention of caries, instruct patient not to rinse, eat or drink for 30 minutes. For patients with rampant or active caries, repeat treatment once or twice every six months.</p> <p>Other information Do not use if safety packaging is broken or missing. Single use only. Store in a dry and cool place.</p> <p>Inactive ingredients Water, Chlorhexidine digluconate, Tromethamine, Trehalose Dihydrate, Oligopeptide-104, Hydroxypropyl Methylcellulose.</p>	<p>Drug Facts</p> <p>Active ingredient Sodium fluoride 0.05% (0.02% w/v fluoride ion) Anticavity</p> <p>Purpose</p> <p>Uses Aids in the prevention of dental cavities. Anticavity dental rinse. Helps prevent decay and cavities, which can keep your enamel strong. Helps prevent decay and white spots.</p> <p>Warning Keep out of reach of children. For topical intraloral use only. For Professional Office Use Only. This product is not intended for home or unsupervised consumer use.</p>
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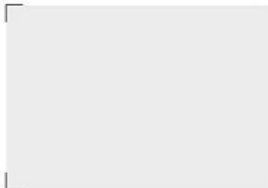
CURODONT™ PLUS REPAIR FLUORIDE

CUROLOX®

Anticavity dental treatment rinse.
Contains 10 single packed single use applicator with 0.1 ml rinse each.

DISTRIBUTED BY STRAUMANN

REF P560.SU



10 x 0.1 ml (10 x 0.033 FL OZ)

Distributed by
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Phone +1 978 747 2500

Manufactured by
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CH-5210 Windisch
Switzerland
product@curodont.us
Phone +41 56 560 20 44

How to use

The general principles for treatment and patient medication must be followed when using CURODONT™ REPAIR Fluoride Plus.

Preparation

- Professional dental cleaning.
- Removal of the pellicle using 2% sodium hypochlorite for 20 seconds.
- Removal of inorganic deposits using 35% phosphoric acid for 20 seconds.
- Rinse the tooth surface with water.
- Dry the tooth surface.



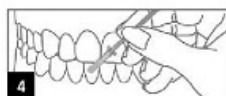
1. Remove safety clip (black).



2. Activate the CURODONT™ REPAIR Fluoride Plus applicator by pushing the two cylinders together.



3. Remove the CURODONT™ REPAIR Fluoride Plus applicator from the protective cover.



4. Apply CURODONT™ REPAIR Fluoride Plus by squeezing out the sponge above the lesion/proximal gap.



5. Allow the solution to diffuse for 5 minutes.
Discard the applicator unit after use.
The applicator is for single use only!

6. Instruct patient not to rinse, eat or drink for 30 minutes.

Additional information

- Repeat treatment at least once or twice a year.
For patients with rampant or active caries, repeat treatment once or twice every six months.
- If contents have become frozen, warm to room temperature.
- For topical intraoral use only.
- For Professional Office Use Only. This product is not intended for home or unsupervised consumer use.

Anticavity dental treatment rinse.
 Contains 1 single packed single use applicator with 0.1 ml (0.033 FL OZ) rinse.
 Aids in the prevention of dental cavities.
 Anticavity dental rinse.
 Helps prevent decay and cavities, which can keep your enamel strong.
 Helps prevent decay and white spots.

DISTRIBUTED BY STRAUMANN

Made in Switzerland

CUROLOX®

CURODONT™ REPAIR FLUORIDE PLUS

Active ingredient

Sodium fluoride 0.05% (0.02% w/v fluoride ion).

Important

Read directions for proper use.



Other information

Do not use if safety packaging is broken or missing. Single use only. Store in a dry and cool place.

Warning

Keep out of reach of children. If more than amount used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away. For topical intraoral use only. For Professional Office Use Only. This product is not intended for home or unsupervised consumer use.

Distributed by

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EXP

LOT

REF P560.SU

CURODONT REPAIR FLUORIDE PLUS

sodium fluoride sponge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72247-105
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNF: 6810107560) (FLUORIDE ION)		0.05%

SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.05 g in 100 mL
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Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E)	
TROMETHAMINE (UNII: 023C2WHX2V)	
TREHALOSE DIHYDRATE (UNII: 7YIN7J07X4)	
OLIGOPEPTIDE-10 (UNII: Q46328TRNK)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72247-105-12	10 in 1 BOX	01/11/2019	
1	NDC:72247-105-11	0.1 mL in 1 CYLINDER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	01/11/2019	

Labeler - CREDENTIS AG (485450345)

Registrant - CREDENTIS AG (485450345)

Establishment

Name	Address	ID/FEI	Business Operations
System Kosmetik Produktionsgesellschaft fur kosmetische Erzeugnisse mbH		328825757	manufacture(72247-105)

Establishment

Name	Address	ID/FEI	Business Operations
VALIDA		480120305	pack(72247-105)

Revised: 1/2020

CREDENTIS AG