

**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.*

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**CREDENTIS (as PLD) - vVardis Professional - CURODONT REPAIR FLUORIDE PLUS (72247-106)**

**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

**WARNINGS**

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. IF MORE THAN USED FOR RINSING IS ACCIDENTALLY SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

**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.

## OTHER INFORMATION



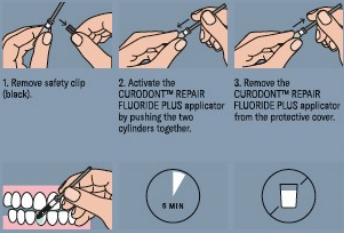

DO NOT USE IF SAFETY PACHAGING IS BROKEN OR MISSING.

SINGLE USE ONLY.

STORE IN A DRY AND COOL PLACE.

## INACTIVE INGREDIENTS

WATER, CHLORHEXIDINE DIGLUCONATE, TROMETHAMINE, TREHALOSE DIHYDRATE, OLIGOPEPTIDE-104, HYDROXYPROPYL METHYLCELLULOSE, CITRIC ACID, SODIUM HYDROXIDE.

 <p>VVARDIS PROFESSIONAL SWITZERLAND</p>	<p><b>How to use</b> The general principles for treatment and patient medication must be followed when using CURODONT™ REPAIR FLUORIDE PLUS.</p> <p><b>Preparation</b></p> <ul style="list-style-type: none"> <li>Professional dental cleaning.</li> <li>Removal of the pellicle using 2 % sodium hypochlorite for 20 seconds.</li> <li>Removal of inorganic deposits using 35 % phosphoric acid for 20 seconds.</li> <li>Rinse the tooth surface with water.</li> <li>Dry the tooth surface.</li> </ul> <p><b>Additional information</b></p> <ul style="list-style-type: none"> <li>If contents have become frozen, warm to room temperature.</li> <li>For topical intraoral use only.</li> <li>For Professional Office Use Only.</li> <li>This product is not intended for home or unsupervised consumer use.</li> </ul>		<p><b>Drug Facts</b></p> <table border="1"> <thead> <tr> <th>Active ingredients</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Sodium fluoride 0.05% (0.02% w/v fluoride ion)</td> <td>Anticavity</td> </tr> </tbody> </table> <p><b>Use</b> Aids in the prevention of dental cavities ■ Anticavity dental rinse ■ Restores enamel ■ For the treatment of white spots</p> <p><b>Warnings</b> <b>Keep out of reach of children.</b> If more than 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.</p> <p><b>Directions</b> 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 &amp; dry the tooth surface. Activate product 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.</p> <p><b>Other information</b> Do not use if safety packaging is broken or missing. Single use only. Store in a dry and cool place.</p> <p><b>Inactive ingredients</b> Water, Chlorhexidine digluconate, Tromethamine, Trehalose Dihydrate, Oligopeptide-104, Hydroxypropyl Methylcellulose, Citric Acid, Sodium Hydroxide.</p>	Active ingredients	Purpose	Sodium fluoride 0.05% (0.02% w/v fluoride ion)	Anticavity
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<p>CURODONT™ REPAIR FLUORIDE PLUS</p> <p>VVARDIS TECHNOLOGY</p> <p>Anticavity dental treatment rinse Contains 10 single packed single use applicators with 0.1 ml rinse each.</p> <p>10 × 0.1 ml (10 × 0.033 FL OZ)</p>	 <ol style="list-style-type: none"> <li>1. Remove safety clip (black).</li> <li>2. Activate the CURODONT™ REPAIR FLUORIDE PLUS applicator by pushing the two cylinders together.</li> <li>3. Remove the CURODONT™ REPAIR FLUORIDE PLUS applicator from the protective cover.</li> <li>4. Apply CURODONT™ REPAIR FLUORIDE PLUS by squeezing out the sponge above the lesion / proximal gap.</li> <li>5. Allow the solution to diffuse for 5 minutes. Discard the applicator unit after use. The applicator is for single use only!</li> <li>6. Instruct patient not to rinse, eat or drink for 30 minutes.</li> </ol> <p>5 MIN</p> <p>IMPORTANT: READ DIRECTIONS FOR PROPER USE.</p>	 <p>Yellow = Unwashed 38 x 40 mm</p> <p>Contact vVartis Inc. 861 N. Broad St. Middletown, DE 19709 United States</p> <p>Manufactured for credentia ag 5210 Windisch Switzerland product@curoidont.us</p>					

## CURODONT REPAIR FLUORIDE PLUS

sodium fluoride sponge

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72247-106
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM MONOFLUOROPHOSPHATE</b> (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.02 g in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CHLORHEXIDINE GLUCONATE</b> (UNII: MOR84MUD8E)	
<b>TROMETHAMINE</b> (UNII: 023C2WHX2V)	
<b>TREHALOSE DIHYDRATE</b> (UNII: 7YIN7J07X4)	
<b>OLIGOPEPTIDE 104</b> (UNII: MUM5TLH7X6)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72247-106-12	10 in 1 BOX	08/27/2023	
1		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	08/27/2023	

**Labeler** - CREDENTIS AG (485450345)

Revised: 8/2023

CREDENTIS AG