CURODONT REPAIR FLUORIDE PLUS- sodium fluoride sponge
CREDENTIS AG

CREDENTIS (Gen 3) - vVardis Professional - CURODONT REPAIR FLUORIDE PLUS (72247-108)

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
- ENAMEL MINERALIZER
- REPAIRS WHITE SPOTS

WARNINGS

FOR TOPICAL USE ONLY.

FOR PROFESSION OFFICE USE ONLY

DO NOT USE

- AT HOME OR FOR 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

- See package insert for specific instructions for product activation
- From the Curodont Repair Fluoride Plus box, retrieve one UNIT A and peel off the color.
- From the pouch, retrieve one UNIT B. Keep the remaining unused UNIT B in the pouch for future use. Do not replace UNIT B with water, saline, or any other liquid. UNIT A and UNIT B are intended to always be used together.
- Pour the entire contents of UNIT B into the UNIT A receptacle containing the sponge, letting it absorb the liquid for at least 5 minutes to fully activate the proprietary formulation. Meanwhile, proceed with preparing the treatment site. Each set of UNIT A and UNIT B is intended to treat one initial lesion in a single patient.
- Perform oral prophylaxis on the teeth to be treated, including removal of the salivary pellicle using your preferred method (pumice/prophy paste/air polisher/2% sodium

hypochlorite). Rinse and dry.
- Etch using 35% phosphoric acid for 20 seconds. For interproximal sites, use unwaxed dental floss to apply the etchant, if needed. Rinse.
- After ensuring that the sponge in UNIT A is fully soaked and soft, isolate the treatment site using basic aids such as cotton rolls, saliva ejector, dry aids, etc. Rubber dam is not necessary.
- Use cotton pliers to firmly grip the saturated sponge in UNIT A from one of its corners.
- Press the sponge on the lesion surface until the formula is deposited and hte sponge starts to appear dry. Use only saturated sponge per lesion. One 'lesion' is defined as one lesion on occlusal/buccal/lingual surfaces or one interproximal site with lesions on one or both adjacent surfaces.
- For interproximal sites, press the saturated sponge starting from lingual embrasure, moving to the buccal and, for any residual formula, the occlusal. Separators or wedges are not needed.
- Wait for 5 minutes before asking the patient to expectorate residues, if any. Dispose the used UNIT A and UNIT B.
- Instruct the patient not to rinse, eat or drink for 30 minutes.

Other information
- Store at room temperature in a dry, cool place
- Single use only
- TAMPER EVIDENT: Do not use if safety packaging seal is broken or missing.

Inactive Ingredients

anhydrous citric acid, chlorhexidine gluconate, hypromellose, oligopeptide-104, sodium hydroxide, trehalose dihydrate, tromethamine, water

Questions? Comments?

Call 1-800-217-0064 or write vVardis Inc., at 651 N. Broad St., Middletown, DE 19709

Anticavity dental treatment rinse. Contains 10 units A and 10 units B

10 x 0.0085 fl. oz. (10 x 0.25 ml)

Drug Facts

Active Ingredients — **Purpose**

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

Use

- Aids in the prevention of dental cavities.
- Anticavity dental rinse
- Enamel remineralizer
- Repairs white spots

Warnings

For Topical Use Only
For Professional Office Use Only

Do not use
- at home or for 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

- See package insert for specific instructions for product activation
- From the Curodont Repair Fluoride Plus box, retrieve one UNIT A and peel off the cover.
- From the pouch, retrieve one UNIT B. Keep the remaining unused UNIT B in the pouch for future use. Do not replace UNIT B with water, saline, or any other liquid. UNIT A and UNIT B are intended to always be used together.
- Pour the entire contents of UNIT B into the UNIT A receptacle containing the sponge, letting it absorb the liquid for at least 5 minutes to fully activate the proprietary formulation. Meanwhile, proceed with preparing the treatment site. Each set of UNIT A and UNIT B is intended to treat one initial lesion in a single patient.
- Perform oral prophylaxis on the teeth to be treated, including removal of the salivary pellicle using your preferred method (pumice/prophy paste/air polisher/2% sodium hypochlorite). Rinse and dry.

Drug Facts (continued)

- Etch using 35 % phosphoric acid for 20 seconds. For interproximal sites, use unwaxed dental floss to apply the etchant, if needed. Rinse.
- After ensuring that the sponge in UNIT A is fully soaked and soft, isolate the treatment site using basic aids such as cotton rolls, saliva ejector, dry aids, etc. Rubber dam is not necessary.
- Use cotton pliers to firmly grip the saturated sponge in UNIT A from one of its corners.
- Press the sponge on the lesion surface until the formula is deposited and the sponge starts to appear dry. Use one saturated sponge per lesion. One 'lesion' is defined as one lesion on occlusal/buccal/lingual surfaces or one interproximal site with lesions on one or both adjacent surfaces.
- For interproximal sites, press the saturated sponge starting from the lingual embrasure, moving to the buccal and, for any additional formula, the occlusal. Separators or wedges are not needed.
- Wait for 5 minutes before asking the patient to expectorate residues, if any. Dispose the used UNIT A and UNIT B.
- Instruct the patient not to rinse, eat or drink for 30 minutes.

Other information

- Store at room temperature in a dry, cool place
- Single use only
- TAMPER EVIDENT: Do not use if safety packaging seal is broken or missing.

Inactive ingredients

anhydrous citric acid, chlorhexidine gluconate, hypromellose, oligopeptide-104, sodium hydroxide, trehalose dihydrate, tromethamine, water

Questions? Comments?

Call 1-800-517-4084 or write Vvardis Inc., at 861 N. Broad St., Middletown, DE 19709

Affordably dental treatment rinse.
Contains 10 units A and 10 units B
10 x 0.0085 fl. oz. (10 x 0.25ml)

FOR PROFESSIONAL USE ONLY
IMPORTANT: READ DIRECTIONS FOR PROPER USE

1x UNIT A AND 1x UNIT B MUST BE USED TOGETHER AND FOR 1 LESION.

CURODONT™ REPAIR
FLUORIDE PLUS

VVARDIS
PROFESSIONAL
SWITZERLAND

NEW IMPROVED DESIGN

NEW IMPROVED DESIGN

THIS PACK CONTAINS

UNIT A — 10 UNITS

UNIT B — 10 UNITS

1x UNIT A AND 1x UNIT B
MUST BE USED TOGETHER AND FOR 1 LESION

VVARDIS
PROFESSIONAL
SWITZERLAND

CURODONT™ REPAIR
FLUORIDE PLUS

Anticavity dental treatment rinse.
Contains 10 units A and 10 units B
10 x 0.0085 fl. oz. (10 x 0.25ml)

FOR PROFESSIONAL USE ONLY
IMPORTANT: READ DIRECTIONS FOR PROPER USE

VVARDIS.COM

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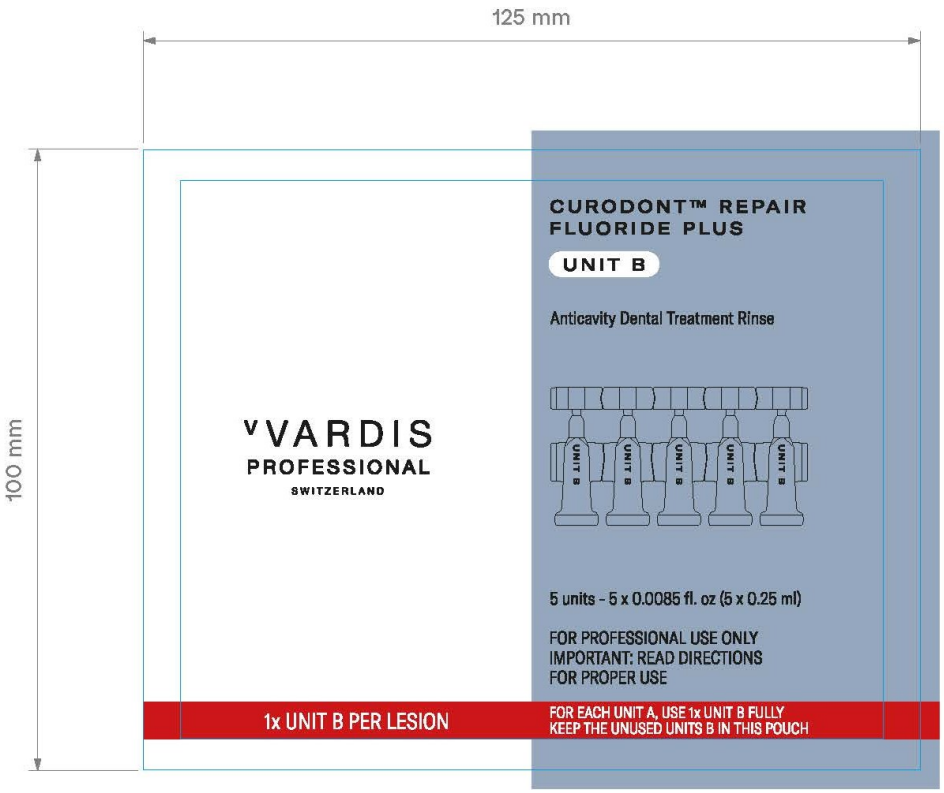
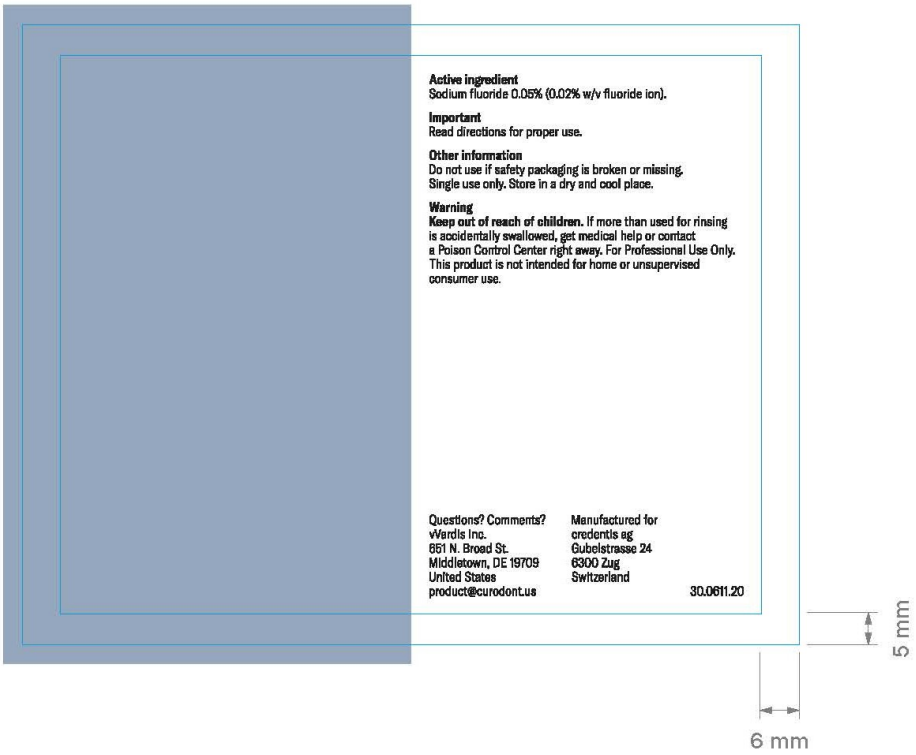
To onboard your clinic, scan below QR code and register in less than 30 seconds:

Manufactured for
curodonts ag
Gubelstrasse 34
6300 Zug
Switzerland

SIZE 100%





CURODONT REPAIR FLUORIDE PLUS

sodium fluoride sponge

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72247-108
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.02 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
OLIGOPEPTIDE-104 (UNII: MUM5TLH7X6)	
TROMETHAMINE (UNII: 023C2WHX2V)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E)	
WATER (UNII: 059QF0KO0R)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
TREHALOSE DIHYDRATE (UNII: 7YIN7J07X4)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:72247-108-03	2 in 1 BOX	12/31/2024	
1	NDC:72247-108-02	5 in 1 POUCH		
1	NDC:72247-108-01	0.25 mL in 1 DOSE PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	12/31/2024	

Labeler - CREDENTIS AG (485450345)

Revised: 12/2024 CREDENTIS AG